Given that a commercial OTEC industry has yet to develop, Part 981 remains unused for the most part. Removal of Part 981 at this time is consistent with the purposes and provisions of the OTEC Act in that it will allow NOAA to evaluate the suitability of these regulations at such time as interest in the commercial development of OTEC projects occurs. At such time, NOAA will issue a proposed rule appropriate to the then current regulatory needs. Potential licensees will therefore be assured that any future OTEC regulations will be up to date, and will continue to provide innovation and flexibility necessary for an emerging OTEC industry.

NOAA is mindful of its responsibility for licensing of commercial OTEC facilities and plantships under the OTEC Act, however, and will take appropriate steps to review and process an application should one be made. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide copies of the provisions of these OTEC regulations in response to such inquiries. Thus, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. § 552(a). Accordingly, NOAA is proposing to remove Part 981, the OTEC regulations, from Title 15 of the CFR.

III. Miscellaneous Rulemaking Requirements

Executive Order 12612: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant the preparation of a Federalism Assessment under Executive Order 12612.

Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

No licenses have been issued for OTEC projects under 15 CFR Part 981. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures and requirements to particular individuals. *See* 5 U.S.C. § 552(a). For these reasons, the proposed removal of Part 981 is not expected to have a significant economic impact on a substantial number of small entities, and the Assistant General Counsel for legislation and Regulation of the Department of Commerce has so certified to the Chief Counsel for Advocacy of the Small Business Administration. As such, an initial Regulatory Flexibility Analysis was not prepared.

Paperwork Reduction Act

This rule does not contain an information collection requirement subject to review and approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3500 *et seq.*

National Environmental Policy Act

NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the human environment. No applications for licenses of commercial OTEC facilities or plantships have yet been received by NOAA, and Part 981 remains unused for the most part. When commercial interest in OTEC projects occurs, NOAA will issue a proposed rule appropriate to the regulatory needs at that time. For particular inquiries into the licensing of OTEC projects in the interim period, NOAA will provide actual and timely notice of applicable procedures to particular individuals. *See* 5 U.S.C. 552(a). Therefore, an environmental impact statement is not required.

Authority: Ocean Thermal Energy Conversion Act of 1980, as amended, 42 U.S.C. 9101 *et seq.*

List of Subjects in 15 CFR Part 981

Administrative practice and procedure, Ocean thermal energy conversion licensing, Environmental protection, Marine resources, Penalties, Reporting and recordkeeping requirements.

Dated: January 24, 1996.

W. Stanley Wilson,

Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, Chapter IX of Title 15 of the Code of Federal Regulations is proposed to be amended as follows:

PART 981—OCEAN THERMAL ENERGY CONVERSION LICENSING PROGRAM—[REMOVED]

1. Under the authority of the Ocean Thermal Energy Conversion Act of 1980, Part 981 is removed.

[FR Doc. 96–1723 Filed 1–29–96; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, 314, and 601

[Docket No. 93N–371W]

Prescription Drug Product Labeling; Public Patient Education Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is reannouncing a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. Previously, in the Federal Register of December 8, 1995 (60 FR 63049), the agency announced this workshop which was scheduled for January 9 and 10, 1996. Due to inclement weather, the agency was forced to postpone the workshop. The agency has rescheduled the workshop for February 14 and 15, 1996. The purpose of this workshop is to obtain views and opinions concerning the criteria for useful patient information, and it is part of FDA's ongoing initiative to improve the distribution of adequate and useful prescription drug information to patients. FDA encourages health professionals, consumer groups, and other interested parties to participate in the workshop. FDA also invites the designers of primary information systems, which produce either written information or computer programs that generate prescription drug patient information, to display their systems for educational purposes.

DATES: The public patient education workshop will be held on February 14 and 15, 1996, from 8:30 a.m. to 5 p.m. Submit registration notices for participants by February 9, 1996. Submit registration notices for designers of information systems by February 7, 1996. Submit written comments by March 6, 1996.

ADDRESSES: The public patient education workshop will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD. Preregistration for workshop participants is encouraged, although not required, in order to facilitate logistical planning of the breakout discussion groups. There is no registration fee for this workshop. Registration forms can be obtained by calling 301–443–5470 or writing to the Office of Health Affairs, ATTN: Patient Education Workshop, Food and Drug Administration (HFY–40), 5600 Fishers

Lane, Rockville, MD 20857. Submit written views or comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The designers of information systems should call the contact person (address below) for registration information. A more detailed agenda and written presentations will be placed in the docket, identified with the docket number found in brackets in the heading of this document, at the Dockets Management Branch, and will be available for review between 9 a.m. and 4 p.m., Monday through Friday. A transcript of the general sessions of the workshop will be available for review or purchase (10 cents per page) at the Dockets Management Branch approximately 5 business days after the meeting. The breakout sessions will not be transcribed.

FOR FURTHER INFORMATION CONTACT: Thomas J. McGinnis, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5470.

SUPPLEMENTARY INFORMATION: On January 9 and 10, 1996, FDA had intended to hold a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. The agency was forced to postpone the workshop due to the closing of the Federal Government because of inclement weather in the metropolitan Washington, DC area. With this notice the agency is announcing the rescheduling of the workshop for February 14 and 15, 1996. The purpose and agenda for the meeting are identical to the previously scheduled workshop, with a few minor changes in the agenda due to the scheduling problems of the original invited presenters.

In the Federal Register of August 24, 1995 (60 FR 44182), FDA published a proposed rule that, if finalized, is intended to increase the dissemination of useful written prescription drug information to patients who receive drugs on an outpatient basis. In that proposal, the agency stated its belief that the quality of medical care could be enhanced and substantial costs from drug misadventures could be reduced by better informing patients about the use, side effects, and interactions of such drugs. At that time, the agency discussed a mandatory Federal program that would require such information to be distributed with most new prescriptions. However, the agency also stated that such a program would not be necessary if private sector efforts now underway accomplished the stated goal. Thus, FDA proposed, except where there is a serious and significant public health concern, to defer its program for several years.

To judge the success of those private efforts, the agency proposed goals (performance standards) that would define acceptable levels of information distribution and quality. To meet the performance standard for distribution of information, the agency proposed that by the year 2000 at least 75 percent of people receiving new prescriptions receive useful information. This goal was adapted from the Public Health Service's ''Healthy People 2000'' report. In addition, the agency proposed that by the year 2006, at least 95 percent of the people who receive new prescriptions receive useful information.

FDA proposed to periodically evaluate and report on the achievement of the goals. If the goals are not met in the specified timeframes, FDA proposed to either: (1) Implement a mandatory comprehensive medication guide program, or (2) seek public comment on whether a comprehensive program should be implemented, or whether, and what, other steps should be taken to meet the patient information goals.

To develop a performance standard for the quality of information distributed, FDA suggested seven specific components in its August 24 proposal for determining whether patient information is useful: Scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility. The agency defined these components of usefulness, as well as criteria that could be used to judge these components, and invited comments on their appropriateness. Because such criteria are of great interest to affected parties, and because there is substantial expertise in the development and communication of patient information, FDA also stated its intention to hold a public meeting that would allow the many interested groups and individuals to provide their recommendations directly to agency officials.

The agency will hold a public patient education workshop to discuss the methods and criteria for developing and evaluating the usefulness of written information. The patient education workshop will be designed to obtain recommendations from the public about the criteria that should be applied to help ensure that written information provided to patients is ''useful.''

The patient education workshop will be comprised of both formal presentations and open breakout discussion periods. Any interested person may attend and participate in the discussions. The workshop will include general sessions with presentations from FDA, health professional groups, consumer groups, the pharmaceutical industry, academicians, and parties with legal and regulatory expertise. The agency also intends to hold breakout sessions the morning of the second day to obtain broad participation and input from workshop attendees.

On Wednesday, February 14, 1996, there will be a series of presentations by consumer organizations, health professional organizations, researchers, and academicians. There will be time set aside for comments and questions from workshop participants. On Thursday, February 15, 1996, workshop participants will be divided into several breakout groups for discussions and development of recommendations regarding elements of useful information. These recommendations will then be presented to the workshop participants with time for comments and questions.

FDA believes that it would be helpful for workshop participants, including FDA staff, to learn about the design of current patient information systems, particularly programs that generate drug-specific patient information. The agency invites the designers of primary information systems, not the customizers of systems for retail outlets, to display their systems at the workshop for educational purposes only. No sales or solicitations may be made by exhibitors at the workshop site. Due to space limitations, FDA may be forced to limit the number of systems on display. In doing so, FDA would seek to permit display of the most representative/comprehensive systems available for patient information. However, the agency invites all interested persons to submit their views, comments, and descriptions of computer programs to the Dockets Management Branch (address above).

The agency notes that the comment period for the proposed rule that published in the Federal Register of August 24, 1995, closed on December 22, 1995 (60 FR 58025, November 24, 1995). Because this workshop will occur after the comment period has closed, the agency will accept additional comments to the proposed rule on the specific issues raised at the workshop. These comments will be considered as part of the agency's deliberations regarding further action on this rulemaking. For this limited purpose, written comments may be submitted to the Dockets Management Branch (address above)

until March 6, 1996. Comments are to be identified with the docket number found in brackets in the heading of this document.

A summary of the workshop will be included in a subsequent Federal Register notice related to this prescription drug labeling initiative.

Dated: January 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1740 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Economic and Business Affairs

22 CFR Part 89

[Public Notice No. 2323]

Foreign Prohibitions on Longshore Work by U.S. Nationals

AGENCY: Department of State.

ACTION: Proposed rule; Extension of comment period.

SUMMARY: On November 24, 1995, the Department of State issued a proposed rulemaking regarding longshore work by foreign nationals in U.S. ports and waters. To assess the full effects of the proposed rule, the Department is extending the deadline for comments by 7 days, from January 26, 1996 to February 2, 1996.

DATES: Interested parties are invited to submit comments in triplicate no later than February 2, 1996.

ADDRESSES: Comments may be mailed to the Office of Maritime and Land Transport (EB/TRA/MA), Room 5828, Department of State, Washington, DC 20520–5816.

FOR FURTHER INFORMATION CONTACT: Richard T. Miller, Office of Maritime and Land Transport, Department of State, (202) 647–6961.

SUPPLEMENTARY INFORMATION: On November 24, 1995, the Department of State issued a proposed rulemaking (60 FR 58026) updating the list of longshore work by particular activity, of countries where performance of such a particular activity by crewmembers aboard United States vessels is prohibited by law, regulation or in practice in the country. The crews of ships registered in or owned by nationals of the countries on the list may not perform the activities enumerated on the list. On December 20, 1995, the Department extended the comment period by thirty days in response to requests from a number of parties (60 FR 65609). To assess the full effects of the proposed rule, the Department is further extending the deadline for comments by one week, from January 26, 1996 to February 2, 1996.

(8 U.S.C. 1288, Pub. L. 010–649, 104 Stat, 4878)

Dated: January 25, 1996.

Daniel K. Tarullo,

Assistant Secretary Economic and Business Affairs Department of State.

[FR Doc. 96–1821 Filed 1–26–96; 10:43 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 630, 635 and 771

[FHWA Docket No. 96–3]

RIN 2125–AD58

Federal-Aid Project Agreement and Contract Procedures

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to amend 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 are being proposed to reflect these adjustments. Additionally, procedures would be added to provide flexibility in the format of the agreement document and to permit the development of a single document to serve as both the project authorization and project agreement document. Other changes would be made to shorten the agreement document and to add clarity to the process.

The FHWA also proposes to amend its regulation on contract procedures by incorporating into it provisions regarding overruns in contract time that would be removed from the project agreement regulation. The FHWA believes this material more appropriately belongs under contract procedures.

DATES: Written comments are due on or before April 1, 1996. Comments received after that date will be considered to the extent practicable.

ADDRESSES: All written, signed comments should refer to the docket number that appears at the top of this document and should be submitted to Federal Highway Administration, Office of Chief Counsel, Room 4232, HCC–10, 400 Seventh Street, SW., Washington, DC 20590. All comments and suggestions received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

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: 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, the State and the Federal shares of a project's cost, and commitments concerning maintenance of the project.

The present regulation, 23 CFR 630, subpart C, provides further requirements concerning the project agreement. It includes detailed instructions on preparation of the project agreement, a standard form for the agreement, and an assemblage of agreement provisions that are part of the standard form. This is a longstanding regulation and no significant changes have been made to it in several years.

It is the FHWA's desire to update and modify the existing regulation to incorporate needed changes to reflect adjustments made 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. The proposed changes are discussed in the following section-by-section analysis.

Section-by-Section Analysis

Section 630.301 Purpose

The statement of purpose would be revised with minor changes for clarity.

Section 630.302 Definitions

It is proposed to remove § 630.302. The terms *calendar day*, *contract time*, *incentives/disincentives for early completion*, *liquidated damages*, and *workday* would be relocated to 23 CFR 635.102. The terms *bond issue project*,