

fees on this sector of the device industry, which plays an important role in fostering innovation.

The negotiated performance goals and commitments that do not have specific timeframes or direct measures of performance set under MDUFMA were comprehensive and demanding. By Fiscal Year (FY) 2007, approximately 85 performance goals and commitments were in effect. FDA provided periodic reports on its progress towards meeting these performance goals and commitments to its stakeholders and Congress. FDA also provided an annual financial report to Congress that helped to ensure transparency and accountability of its use of the additional resources provided by MDUFMA.

In 2007, Congress reauthorized medical device user fees through FY 2012 under the Medical Device User Fee Amendments of 2007 (MDUFA) (title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85).

Under MDUFA, the user fee program remained intact, with a few significant modifications to the program. The user fee framework was changed to provide a more reliable and stable funding stream. Specifically, MDUFA included establishment registration as a new fee type that provided a more predictable amount of funds that could be collected by the Agency in any given year. MDUFA also saw changes to the performance goals. Compared to MDUFMA, there were fewer performance goals under MDUFA, yet the goals were more demanding. Specifically, individual cycle goals were removed and tighter overall goals were implemented. This was done to facilitate a more interactive review process. Specific timelines were established under MDUFA for Modular Premarket Approvals (PMAs) and Real-Time PMA supplements, which were not included under MDUFMA in 2002. The commitment letter outlining the goals in the last reauthorization can be found at <http://www.fda.gov/MDUFA>. FDA published a number of reports that provide the public with useful background on MDUFMA, FDAAA, and MDUFA. Key **Federal Register** documents, MDUFA-related guidance documents, legislation, performance reports, and financial reports and plans can be found at <http://www.fda.gov/MDUFA>. FDA will also post a webinar on the medical device user fee program to give the public more background information on the program. The webinar will be available through the link to the Public Meeting at <http://www.fda.gov/MedicalDevices/>

NewsEvents/WorkshopsConferences/ucm218250.htm approximately 10 days before the public meeting. FDAAA specific information is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/SignificantAmendmentsToTheFDCA/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this notice, we are announcing a public meeting to hear stakeholder views on the reauthorization of the medical device user fee program, including specific suggestions for any changes to the program that we should consider. We will conduct the meeting on September 14, 2010. In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection, industry, health professionals, and academic researchers). We will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on program improvements and funding issues, including specific suggestions for changes to performance goals, and not focus on policy issues.

B. What Questions Would FDA Like the Public to Consider?

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the medical device user fee program thus far?
2. What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?

C. Will Meeting Transcripts be Available?

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of

Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: August 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19843 Filed 8–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2009–0097]

Notice of Availability of Final Environmental Impact Statement for the Goethals Bridge Replacement Project

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of the Final Environmental Impact Statement for the proposed replacement by the Port Authority of New York and New Jersey of the 82-year old Goethals Bridge across the Arthur Kill between Staten Island, NY, and Elizabeth, NJ. The FEIS analyzes the potential for impact to the natural, human and cultural environment of the proposed Goethals Bridge Replacement Project.

DATES: The review period for the FEIS will close on September 13, 2010. Comments and related material must either be submitted to our online docket via <http://www.regulations.gov> on or before September 13, 2010 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2009–0097 using any one of the following methods:

- (1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.
- (2) *Fax:* 202–493–2251.
- (3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.
- (4) *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section below for instructions on how to submit comments.

The First Coast Guard District Bridge Office located at One South Street, Battery Park Building, New York, NY 10004, will maintain a printed copy of the FEIS available for inspection or copying between 9 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding this notice, call or e-mail Gary Kassof, Bridge Program Manager, First Coast Guard District, U.S. Coast Guard; telephone 212-668-7165, e-mail gary.kassof@uscg.mil. If you have questions regarding viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation

Submitting Comments: If you submit a comment, please include the docket number for this notice (USCG-2009-0097) and provide a reason for each suggestion or recommendation. You may submit your comments and material online, or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Notices" and insert "USCG-2009-0097" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing the Comments and the FEIS: To view the comments and the FEIS, go to <http://www.regulations.gov>, click on the "read comments" box, which will

then become highlighted in blue. In the "Keyword" box insert "USCG-2009-0097" and click "Search." Click the "Open Docket Folder" in the "Actions" column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act: Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act, system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Background and Purpose

The Port Authority of New York and New Jersey (Port Authority), a transportation and development agency for the Port of New York and New Jersey, has proposed replacement of the functionally and physically obsolete Goethals Bridge that carries I-278 vehicular traffic between Staten Island, NY, and Elizabeth, NJ. On May 28, 2009 (74 FR 25572), the USCG made available the Draft EIS (DEIS). Two formal public meetings were held, on July 8 and 9, 2009, to provide an opportunity for submittal of oral comments to the USCG; written comments were accepted by the USCG through July 28, 2009.

Following the close of the public comment period in July 2009, the Port Authority, the project sponsor, chose the New Alignment South as its proposed alignment, and the USCG, the lead Federal agency for the NEPA process, has identified the New Alignment South as the Preferred Alternative for presentation and evaluation in the FEIS. The Preferred Alternative comprises a new cable-stayed replacement bridge on an alignment south of the existing Goethals Bridge, and removal of the existing bridge following construction of the new bridge. The replacement bridge would comprise the following elements: Six 12-foot-wide travel lanes, three on each of two roadway decks (one roadway for eastbound traffic and one roadway for westbound traffic); a 12-foot-wide outer shoulder and a 5-foot-wide inner shoulder on each roadway; a minimum 10-foot-wide sidewalk/

bikeway along the northern edge of the westbound roadway; and a 65-foot-wide central area to be maintained between the east- and westbound decks to accommodate the towers and support cables as well as to allow for the provision of mass transit service, should future conditions warrant inclusion of such service during the service life of the replacement bridge. Navigational clearance beneath the new bridge is proposed to be a minimum of 135 feet above mean high water (MHW) at the channel margins; similar to the current minimum vertical clearance of the existing bridge. The main piers are proposed to be constructed 900 feet apart, an increase from the existing horizontal separation of 672 feet; thereby moving all bridge structure-related hazards further away from the 500-foot wide federally maintained navigation channel of the Arthur Kill. The elevation of the two bridge towers is proposed to be 272 feet above mean sea level (MSL), as compared to the 248 feet above MSL associated with the existing bridge's truss superstructure.

As a structure over navigable waters of the United States, any replacement bridge requires a U.S. Coast Guard (USCG) Bridge Permit pursuant to the General Bridge Act of 1946 (Title 33 U.S.C. 525-533). Additionally, the bridge permit would be the major federal action in this undertaking. The USCG, a component of the Department of Homeland Security (DHS), by virtue of its regulatory authority over bridges across navigable waters of the United States, is the lead Federal agency for review of potential effects on the human environment, including historic properties, of the Preferred Alternative, three alternative alignments for construction and operation of a replacement bridge, and the No Build alternative. The FEIS was prepared pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*).

This notice is issued under authority of the Administrative Procedure Act (5 U.S.C. 553(c)); the General Bridge Act of 1946 (Title 33 U.S.C. 525-533); and the National Environmental Policy Act (NEPA) of 1969 (Section 102(2)(c)), as implemented by the Council on Environmental Quality regulations (40 CFR parts 1500-1508), Department of Homeland Security Directive 023-01, and Coast Guard Commandant Instruction M16475.1D.

Given the Findings of Adverse Effect on three historic properties (including the existing Goethals Bridge) and the ongoing development of a Memorandum of Agreement (MOA) as per Section 106 of the National Historic Preservation Act

(NHPA), as amended (16 U.S.C. 470 *et seq.*), this notice also serves as an instrument for integration of the Section 106 Consultation into the NEPA process, as required under 40 CFR 1505.25(a); as well as 36 CFR 800.2(a)(4), 800.3(b) and 800.8. An MOA for the Preferred Alternative will be executed in consultation with the New York and New Jersey State Historic Preservation Offices, and will be completed prior to the anticipated record of decision (ROD) at the culmination of the NEPA process.

In accordance with the applicable regulations of the General Conformity Rule (pursuant to the Clean Air Act; 42 U.S.C. 7401 *et seq.* as amended) and given the findings that the estimated annual emission rates of two pollutants (*i.e.*, CO and NO_x) are predicted to exceed the General Conformity applicability thresholds during the GBR Project's construction period, this notice also serves as the instrument to fulfill the 30-day public review requirements for the General Conformity Determination by the USCG.

Absent new information coming to its attention prior to the conclusion of the 30-day period, the Coast Guard intends to complete its ROD and pursue the preferred alternative at that time. The ROD will identify the environmentally-preferred alternative for the proposed action and be announced in the **Federal Register**.

Dated: August 3, 2010.

Hala Elgaaly,

Administrator, Bridge Program, United States Coast Guard.

[FR Doc. 2010-19630 Filed 8-12-10; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1931-DR; Docket ID FEMA-2010-0002]

Texas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FEMA-1931-DR), dated August 3, 2010, and related determinations.

DATES: *Effective Date:* August 3, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate,

Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 3, 2010, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Texas resulting from Hurricane Alex beginning on June 30, 2010, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Texas.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance, Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Bradley M. Harris, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Texas have been designated as adversely affected by this major disaster:

Cameron, Hidalgo, Jim Hogg, Maverick, Starr, Val Verde, Webb, and Zapata Counties for Individual Assistance.

Cameron, Hidalgo, Jim Hogg, Jim Wells, Maverick, Starr, Webb, Willacy, and Zapata Counties for Public Assistance.

All counties within the State of Texas are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora

Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-20007 Filed 8-12-10; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2010-0048]

Recovery Policy, RP9525.16, Research-Related Equipment and Furnishings

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) is accepting comments on Recovery Policy RP9525.16 *Research-related Equipment and Furnishings*. This is an existing policy that is scheduled for review to ensure that Recovery Directorate policies are consistent with current laws and regulations. This policy identifies the expenses associated with disaster-damaged research-related equipment and furnishings of eligible private nonprofit or public facilities that are eligible for reimbursement under the Public Assistance Program.

DATES: Comments must be received by September 13, 2010.

ADDRESSES: Comments must be identified by docket ID FEMA-2010-0048 and may be submitted by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Please note that this proposed policy is not a rulemaking and the Federal Rulemaking Portal is being utilized only as a mechanism for receiving comments.

Mail: Rules Docket Manager, Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street, SW., Washington, DC 20472-3100.