# 35655

# TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2004, THROUGH MARCH 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P970020(S40)/2004M-0024	Guidant Corp.	ACS MULTI–LINK RX/OTW DUET CORONARY STENT SYSTEMS	August 6, 2002
P890064(S9)/2004M-0147	Digene Corp.	DIGENE HYBRID CAPTURE 2 (HC2) HIGH-RISK HPV DNA TEST	March 31, 2003
P020006/2004M-0145	Enteric Medical Technologies, Inc.	ENTERYX PROCEDURE KIT	April 22, 2003
P020031/2004M-0031	Microsulis Corp.	MICROSULIS MICROWAVE ENDOMETRIAL ABLATION	September 23, 2003
P010059/2004M-0022	Morcher GMBH	MORCHER CAPSULAR TEN- SION RING, TYPES 14, 14A, and 14C	October 23, 2003
P030002/2004M-0012	Eyeonics, Inc.	CRYSTALENS MODEL AT-45 ACCOMMODATING POS- TERIOR CHAMBER INTRA- OCULAR LENS	November 14, 2003
P030005/2004M-0064	Guidant Corp.	CONTAK RENEWAL MODELS H125 and H120 WITH MODEL 2865 VERSION 1.8 APPLICA- TION SOFTWARE	January 26, 2004
P030006/2004M-0116	Celsion Corp.	PROLIEVE THERMODILATION SYSTEM	February 19, 2004
H030004/2004M-0084	Menssana Research, Inc.	HEARTSBREATH	February 24, 2004
H030003/2004M-0090	MicroMed Technology, Inc.	DEBAKEY VAD CHILD LEFT VENTRICULAR ASSIST SYS- TEM	February 25, 2004
P010018(S5)/2004M-0134	Refractec, Inc.	VIEWPOINT CK SYSTEM	March 16, 2004

# II. Electronic Access

Persons with access to the Internet may obtain the documents at *http:// www.fda.gov/cdrh/pmapage.html*.

Dated: June 7, 2004.

#### Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–14439 Filed 6–24–04; 8:45 am] BILLING CODE 4160–01–S

# DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

# DEPARTMENT OF TRANSPORTATION

#### Maritime Administration

[USCG-2004-16860]

# Gulf Landing LLC Liquefied Natural Gas Deepwater Port License Application; Draft Environmental Impact Statement

**AGENCY:** Coast Guard, DHS; and Maritime Administration, DOT. **ACTION:** Notice of availability; notice of public meeting; and request for public comments.

**SUMMARY:** The Coast Guard and the Maritime Administration announce the availability of the draft environmental impact statement for the Gulf Landing, LLC Deepwater Port License Application. The proposed Gulf Landing liquefied natural gas deepwater port would be located in the Gulf of Mexico approximately 38 miles south of Cameron, Louisiana. The Coast Guard and the Maritime Administration solicit public input on this draft environmental impact statement.

**DATES:** The draft environmental impact statement (DEIS) will be available on June 25, 2004, and comments must reach the Coast Guard on or before August 9, 2004. Additionally, an informational open house will be held in Lafayette, Louisiana on July 15, 2004, from 2 p.m. until 4 p.m., and a formal public meeting from 5 p.m. until 7 p.m. **ADDRESSES:** The informational open house/public meeting location is: Courtyard by Marriott, 214 East Kaliste Saloon Road, Lafayette, LA 70508, telephone number 337–232–5005.

You may submit comments, identified by Coast Guard docket number USCG– 2004–16860, to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods: Web site: http://dms.dot.gov.
Mail: Docket Management Facility,
U.S. Department of Transportation, 400
Seventh Street SW., Washington, DC
20590–0001.

(3) Fax: 202-493-2251.

(4) *Delivery:* Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366– 9329.

(5) Federal eRulemaking Portal: http://www.regulations.gov.

The Docket Management Facility maintains the public docket for this notice. Comments will become part of this docket and will be available for inspection or copying in Room PL-401, located on the Plaza Level of the Nassif Building at the above address between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays. You may also view this docket, including this notice and comments, on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, the project, or the meeting, call Lieutenant Derek Dostie at 202–267–0662, or e-mail at *ddostie@comdt.uscg.mil*. If you have questions on viewing or submitting material to the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271.

#### SUPPLEMENTARY INFORMATION:

#### **Request for Comments**

We encourage you to submit comments on the DEIS. You may submit comments and related materials on this notice, the public meeting, or concerning the license application. Persons submitting comments should include their name and address, the docket number (USCG-2004-16860), and the reasons for each comment. You may submit your comments and materials by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address given under ADDRESSES; but please submit your comments and materials by only one means. If you choose to submit them by mail or hand delivery, submit them in an unbound format, no larger than 8<sup>1</sup>/<sub>2</sub> by 11 inches, and suitable for copying and electronic filing. If you submit them by mail and would like to know if they reach the facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and materials received during the comment period. All comments received will be posted, without change, to http://dms.dot.gov and will include any personal

information you have provided. We have an agreement with the Department of Transportation (DOT) to use their Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

#### **Viewing Comments and Documents**

To view comments, the DEIS, or other materials relating to this license application, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

# **Privacy Act**

Anyone can search the electronic form of all 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http:// dms.dot.gov.* 

# Public Meeting/Informational Open House

The Coast Guard and the Maritime Administration will host an informational open house from 2 p.m. to 4 p.m. on Thursday, July 15, 2004, at the Courtyard by Marriott, 214 East Kaliste Saloon Road, Lafayette, LA 70508, telephone number 337-232-5005. A public meeting will be held from 5 p.m. until 7 p.m., following the informational open house. We invite the public and representatives of interested agencies to attend and provide their views on the proposed action and the evaluation contained in the DEIS. If you plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, please contact the person named in FOR FURTHER **INFORMATION CONTACT** and we will try to make reasonable accommodations for your needs. We ask that any requests be made at least three (3) business days prior to the scheduled meeting and include a contact person's name, telephone number, your specific need, and a TDD number (for those with hearing impairments).

# **Proposed Action**

The application plan calls for construction of a deepwater port and associated anchorages in an area situated in the Gulf of Mexico, approximately 38 miles south of Cameron, Louisiana, in outer continental shelf block West Cameron 213, in water depth of approximately 55 feet, and adjacent to an existing shipping fairway servicing the Calcasieu River and area ports.

Gulf Landing's terminal would be capable of storing up to 200,000 cubic meters of LNG and vaporizing up to 1.2 billion cubic feet per day. Gulf Landing proposes to construct, own, and operate 5 pipelines that would interconnect with existing natural gas pipelines located in the Gulf of Mexico. Gas would then be delivered to the onshore national pipeline grid for delivery to any consumption market east of the Rocky Mountains.

The project would consist of two concrete gravity based structures (GBSs) housing the LNG containment facilities, along with topside unloading and vaporization structures, living quarters, and a ship berthing system.

The terminal would be able to receive LNG carriers with cargo capacities between 125,000 and 200,000 cubic meters and unload up to 135 LNG carriers per year. LNG carrier arrival frequency would be planned to match specified terminal gas delivery rates. All marine systems, communication, navigation aids and equipment necessary to conduct safe LNG carrier operations and receiving of cargo during specified atmospheric and sea states would be provided at the port.

The regasification process would consist of lifting the LNG from storage tanks, pumping the cold liquid to pipeline pressure, subsequent vaporization of the LNG across heat exchanging equipment, and send-out through custody transfer metering to the gas pipeline network. No gas conditioning is required at the terminal since the incoming LNG would be pipeline quality.

<sup>1</sup> Five offshore pipelines, ranging from 16 to 36 inches in diameter, would be constructed and would transverse a combined 65.7 nautical miles. Each pipeline would transport gas from the terminal to an existing transmission pipeline where it would deliver the gas to the onshore U.S. gas pipeline network. On average, Gulf Landing expects the terminal would vaporize and deliver 1 billion cubic feet per day (Bcfd) of natural gas to the pipelines; with a peak daily send-out rate of 1.2 Bcfd.

#### Alternatives

The DEIS examines the preferred location, an alternative site and a noaction alternative. The alternative project site is West Cameron block 183. The DEIS will assess the impacts of the alternatives—including approving, approving with conditions, or not approving (No Action Alternative) the license application to construct and operate Gulf Landing—on the natural and human environment.

As required by the National Environmental Policy Act, the Coast Guard also will analyze the No Action Alternative as a baseline for comparing the impacts of the proposed project. For the purposes of this project, the No Action Alternative is defined as not approving the Gulf Landing LLC Deepwater Port License Application.

Dated: June 21, 2004.

# Howard L. Hime,

Acting Director of Standards, Marine Safety, Security, and Environmental Protection, U.S. Coast Guard.

#### Raymond R. Barberesi,

Director, Office of Ports and Domestic Shipping, U.S. Maritime Administration. [FR Doc. 04–14456 Filed 6–22–04; 1:22 pm] BILLING CODE 4910-15-P

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

# DEPARTMENT OF TRANSPORTATION

#### **Maritime Administration**

[USCG-2004-17659]

## Compass Port LLC Liquefied Natural Gas Deepwater Port License Application; Preparation of Environmental Impact Statement

**AGENCY:** Coast Guard, DHS; and Maritime Administration, DOT. **ACTION:** Notice of intent; notice of public meeting; and request for public comments.

**SUMMARY:** The U.S. Coast Guard and the Maritime Administration announce that the Coast Guard intends to prepare an environmental impact statement as part of the environmental review of the license application for the proposed Compass Port deepwater port, to be located approximately 11 miles south of Dauphin Island, Alabama. Publication of this notice begins a public scoping process that will help determine the scope of issues to be addressed in the environmental impact statement and identify the significant environmental issues related to this license application. Finally, this notice solicits public involvement in the scoping process, and announces public meetings and a public comment period to facilitate that involvement.

**DATES:** The public meetings will be held July 12, 13, and 14, 2004, from 3 p.m. to 7 p.m. in Dauphin Island, Alabama, Mobile, Alabama, and Pascagoula, Mississippi, respectively. Each meeting will consist of an informational open house from 3 p.m. to 4:30 p.m. and a public scoping meeting from 5 p.m. to 7 p.m. Comments and related material must reach the docket on or before July 26, 2004.

#### ADDRESSES:

- The Dauphin Island meetings will be held at:
  - Dauphin Island Chamber of Commerce, 402 La Vente Street, Dauphin Island, Alabama 36528, 251–861–5524.
- The Mobile meetings will be held at: Mobile Government Plaza, 205 Government Street, Mobile, Alabama 36644, 251–574–5058.
- The Pascagoula meetings will be held at: Jackson County Fairgrounds Fair Hall, 2902 Shortcut Road, Pascagoula, Mississippi 39567, 228–762–6043.
- All meeting spaces will be wheelchairaccessible.

You need not attend the meetings in order to comment. You may also submit comments identified by docket number USCG-2004-17659 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Electronically through the Web site for the Docket Management System, at *http://dms.dot.gov.* 

(2) By mail to the Docket Management Facility, U.S. Department of Transportation, Room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) By delivery to Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366– 9329.

(5) By the Federal eRulemaking Portal at *http://www.regulations.gov/.* 

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public will become part of this docket and will be available for inspection or copying in Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, from 9 a.m. to 5 p.m. Monday through Friday, except Federal holidays. This docket may also be found on the Internet at http://dms.dot.gov. FOR FURTHER INFORMATION CONTACT: If you have questions on the application, this notice, or the meetings, or if you want to be notified when the draft and final environmental impact statements become available, call Mr. Kenneth Smith at 202–267–0578, or email at *KNSmith@comdt.uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271. SUPPLEMENTARY INFORMATION:

# Scoping Meetings and Request for

# Comments

We seek public review of and comment on this license application, particularly with respect to the environmental review discussed in this notice. Public input on environmental concerns related to the application, suggested sources of relevant data, and suggested methods for environmental analysis are especially welcome.

The Coast Guard will hold informational open houses and scoping meetings for interested members of the public, as described under DATES and **ADDRESSES.** Meeting facilities are wheelchair accessible. If you need other special assistance in order to participate in these sessions (for example, sign language interpretation), please contact the person named in FOR FURTHER **INFORMATION CONTACT.** and we will try to make reasonable accommodation for your needs. We ask that you make such requests at least three (3) business days before the scheduled meeting. Include a contact person's name and telephone number, your specific need, and (for persons with hearing impairments) a TDD number.

If you submit comments or related material to the docket (see DATES and ADDRESSES), please make your comment as specific as possible and give us the reasons for each comment. If you mail or hand-deliver printed documents, please submit them unbound and in a format suitable for copying and electronic filing, no larger than 81/2 by 11 inches. If you submit comments or material by mail and want confirmation that it has reached the facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. All comments received will be posted, without change, to *http://dms.dot.gov/* and will include any personal information you have provided.

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on