

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug and Biological Product Consolidation; Investigational New Drug Application Number Conversion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Drug Evaluation and Research (CDER) will assign new numbers to a group of investigational new drug applications (INDs). In 2003, FDA transferred certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to CDER. The consolidation of INDs transferred from CBER with CDER INDs resulted in INDs with duplicate numbers. To resolve this issue, CDER is renumbering some INDs that were submitted to CDER before the consolidation. This **Federal Register** notice serves to notify sponsors in lieu of sending letters to them.

ADDRESSES: Information on CDER IND renumbering is available on the Internet at <http://www.fda.gov/cder/regulatory/applications/INDrenumbering.htm>.

FOR FURTHER INFORMATION CONTACT: Samuel Y. Wu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., bldg. WO22, rm. 1121, Silver Spring, MD 20993, 301-796-0637.

SUPPLEMENTARY INFORMATION:

I. Therapeutic Biological Products Transferred to CDER

On October 1, 2003, FDA transferred responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines), from the Office of Therapeutics Research and Review, CBER, to the Office of New Drugs, CDER, and the Office of Pharmaceutical Science, CDER (68 FR 38067, June 26, 2003). Applications for the therapeutic biological products now under CDER's review—including INDs, biologics license applications, investigational device exemptions, and new drug applications—were transferred to CDER. For more information on the transfer of therapeutic biological products from CBER to CDER, see FDA's Web site <http://www.fda.gov/cber/transfer/transfer.htm>.

II. Duplicate IND Numbers

The consolidation of INDs transferred from CBER to CDER has resulted in duplicate IND numbers. To resolve this issue, INDs numbered below 14,000 that were submitted to CDER before the consolidation will be assigned new numbers. To determine the new number, CDER has added 80,000 to the original IND number. For example, IND 8,999 will become IND 88,999 and IND 11,192 will become 91,192. INDs that were originally submitted to CBER and transferred to CDER will retain their numbers.

III. Web Site for Information on Renumbered INDs

FDA has created a Web site with more detailed information about the IND number conversion scheme. The Web site address is <http://www.fda.gov/cder/regulatory/applications/INDrenumbering.htm>.

Dated: November 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-22802 Filed 11-16-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of a Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council in December 2005.

The SAMHSA National Advisory Council will meet in an open session December 6 from 9 a.m. to 5:30 p.m. and on December 7 from 9 a.m. to 12:30 p.m. The meeting will include a SAMHSA Administrator's Report, presentations on SAMHSA's response to Hurricanes Katrina and Rita, discussions concerning issues on SAMHSA's appropriation and budget, and discussions on current administrative, legislative and program developments. In addition, the recipients of two SAMHSA-funded model programs will describe their approaches to prevent and treat substance abuse and mental health disorders. On December 7, the Race Against Drugs Motorcar will be on display in the SAMHSA parking lot.

Attendance by the public at the meeting will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to

make arrangements to comment or to request special accommodations for persons with disabilities.

Substantive program information, a summary of the meeting, and a roster of Council members will be available, as soon as possible after the meeting, either by accessing the SAMHSA Council Web site, www.samhsa.gov/council/council, or may be obtained by communicating with the contact whose name and telephone number is listed below. The transcript for the meeting will also be available on the SAMHSA Council Web site within three weeks after the meeting.

Committee Name: SAMHSA National Advisory Council.

Date/Time: Tuesday, December 6, 2005, 9 a.m. to 5:30 p.m. (Open). Wednesday, December 7, 2005, 9 a.m. to 12:30 p.m. (Open).

Place: 1 Choke Cherry Road, Sugarloaf and Seneca Conference Rooms, Rockville, Maryland 20857.

Contact: Toian Vaughn, Executive Secretary, SAMHSA National Advisory Council and SAMHSA Committee Management Officer, 1 Choke Cherry Road, Room 8-1089, Rockville, Maryland 20857. Telephone: (240) 276-2307; FAX: (240) 276-2220 and E-mail: toian.vaughn@samhsa.hhs.gov.

Dated: November 10, 2005.

Toian Vaughn,

Executive Secretary, SAMHSA National Advisory Council and SAMHSA Committee Management Officer.

[FR Doc. 05-22788 Filed 11-16-05; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[COTP Mobile-05-051]

Notice, Request for Comments; Letter of Recommendation, Gulf LNG Clean Energy Marine Terminal Project, Jackson County, MS

AGENCY: Coast Guard, DHS.

ACTION: Request for comments; notice of public meeting.

SUMMARY: In accordance with the requirements in 33 CFR 127.009, the U.S. Coast Guard Captain of the Port (COTP) Mobile, AL is preparing a letter of recommendation as to the suitability of the Pascagoula Bar, Horn Island Pass, Lower Pascagoula, and Bayou Casotte Channels for liquefied natural gas (LNG) marine traffic. The letter of recommendation is in response to a letter of intent submitted by Gulf LNG

Clean Energy Marine Terminal Project to operate a LNG facility in Jackson County, MS. The COTP Mobile, AL is soliciting written comments and related material, and will hold a public meeting seeking comments, pertaining specifically to maritime safety and security aspects of the proposed LNG facilities. In preparation for issuance of a letter of recommendation and the completion of certain other regulatory mandates, the COTP Mobile, AL will consider comments received from the public as input into a formalized risk assessment process. This process will assess the safety and security aspects of the facility, adjacent port areas, and navigable waterways.

DATES: All written comments and related material must reach the Coast Guard on or before December 14, 2005. In addition, a public meeting will be held December 7, 2005 from 5 p.m. to 7 p.m. local time. Those who plan to speak at the meeting should provide their name by December 2, 2005 to Lieutenant (Junior Grade) J. Mangum using one of the methods listed under **FOR FURTHER INFORMATION CONTACT**. The comment period associated with the public meeting will remain open for seven days following the meeting. The meeting location is: Pascagoula High School, 1716 Tucker Ave, Pascagoula, MS.

ADDRESSES: You may submit written comments to Commanding Officer, U.S. Coast Guard Sector Mobile, Brookley Complex, Bldg 102, South Broad Street, Mobile, AL 36615-1390. Sector Mobile maintains a file for this notice. Comments and material received will become part of this file and will be available for inspection and copying at Sector Mobile between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact Lieutenant (Junior Grade) J. Mangum at Coast Guard Sector Mobile by one of the methods listed below:

- (1) Phone at 251-441-5940;
- (2) E-mail at

jmangum@msomobile.uscg.mil;

- (3) Fax to 251-441-6169.

SUPPLEMENTARY INFORMATION:

Request for Written Comments

We encourage you to submit written comments and related material pertaining specifically to marine safety and security aspects associated with the proposed LNG facilities. If you do so, please include your name and address, identify the docket number for this notice (COTP Mobile-05-051), and give the reason for each comment. You may

submit your comments and related material by mail, or hand delivery, as described in **ADDRESSES**, or you may send them by fax or e-mail using the contact information under **FOR FURTHER INFORMATION CONTACT**. To avoid confusion and duplication, please submit your comments and material by only one means.

If you submit 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 U.S. Coast Guard Sector Mobile, please enclose a stamped, self-addressed postcard or envelope.

Public Meeting

Due to the scope and complexity of this project, we have decided to hold a public meeting to allow the public the opportunity to comment on the proposed LNG facility. With advance notice, organizations and members of the public may provide oral statements regarding the suitability of the Pascagoula Bar, Horn Island Pass, Lower Pascagoula, and Bayou Casotte Channels for LNG vessel traffic. In the interest of time and use of the public meeting facility, oral statements should be limited to five minutes. Persons wishing to make oral statements should notify Lieutenant (Junior Grade) J. Mangum using one of the methods listed under **FOR FURTHER INFORMATION CONTACT** by December 2, 2005. Written comments may be submitted at the meeting or to the Docket up to December 14, 2005.

Background and Purpose

In accordance with the requirements of 33 CFR 127.007, Gulf LNG Energy, LLC submitted a Letter of Intent on December 3, 2004, to operate an LNG facility in Jackson County, MS.

The proposed Gulf LNG Energy, LLC terminal is an LNG import, storage, and re-gasification facility. LNG carriers (ships) would berth at a new pier and LNG would be transferred by pipeline from the carriers to one of two storage tanks, each with a net capacity of 160,000 cubic meters (m3) and a gross capacity of 320,000 m3. The LNG would then be regasified and metered into natural gas pipelines. LNG would be delivered to the terminal in double-hulled LNG carriers ranging in capacity from 88,000 m3 to 150,000 m3. The larger carriers would measure up to approximately 975 feet long with up to approximately a 150 foot wide beam, and draw 37 feet of water. The Gulf LNG Energy LLC terminal would handle approximately 150 vessels per year, depending upon natural gas demand,

and carrier size, with shipments arriving about every 2.5 days.

The U.S. Coast Guard exercises regulatory authority over LNG facilities which affect the safety and security of port areas and navigable waterways under Executive Order 10173, the Magnuson Act (50 U.S.C. 191), the Ports and Waterways Safety Act of 1972, as amended (33 U.S.C. 1221, *et seq.*) and the Maritime Transportation Security Act of 2002 (46 U.S.C. 701). The Coast Guard is responsible for matters related to navigation safety, vessel engineering and safety standards, and all matters pertaining to the safety of facilities or equipment located in or adjacent to navigable waters up to the last valve immediately before the receiving tanks. The Coast Guard also has authority for LNG facility security plan review, approval, and compliance verification as provided in Title 33 CFR Part 105, and siting as it pertains to the management of vessel traffic in and around the LNG facility.

Upon receipt of a letter of intent from an owner or operator intending to build a new LNG facility, the Coast Guard COTP conducts an analysis that results in a letter of recommendation issued to the owner or operator and to the state and local governments having jurisdiction, addressing the suitability of the waterway to accommodate LNG vessels. Specifically, the letter of recommendation addresses the suitability of the waterway based on:

- The physical location and layout of the facility and its berthing and mooring arrangements.
- The LNG vessels' characteristics and the frequency of LNG shipments to the facility.
- Commercial, industrial, environmentally sensitive, and residential areas in and adjacent to the waterway used by the LNG vessels en route to the facility.
- Density and character of marine traffic on the waterway.
- Bridges or other manmade obstructions in the waterway.
- Depth of water.
- Tidal range.
- Natural hazards, including rocks and sandbars.
- Underwater pipelines and cables.
- Distance of berthed LNG vessels from the channel, and the width of the channel.

In addition, the Coast Guard will review and approve the facility's operations manual and emergency response plan (33 CFR 127.019), as well as the facility's security plan (33 CFR 105.410). The Coast Guard will also provide input to other Federal, State, and local

government agencies reviewing the project. Under an interagency agreement the Coast Guard will provide input to, and coordinate with, the Federal Energy Regulatory Commission (FERC), the lead Federal agency for authorizing the siting and construction of onshore LNG facilities, on safety and security aspects of the Gulf LNG Energy, LLC terminal project, including both the marine and land-based aspects of the project.

In order to complete a thorough analysis and fulfill the regulatory mandates cited above, the COTP Mobile, AL will be conducting a formal risk assessment, evaluating various safety and security aspects associated with the proposed Gulf LNG Clean Energy Marine Terminal Project. This risk assessment will be accomplished through a series of workshops focusing on the areas of waterways safety, port security, and consequence management, with involvement from a broad cross-section of government and port stakeholders with expertise in each of the respective areas. The workshops will be by invitation only. However, comments received during the public comment period will be considered as input into the risk assessment process.

Additional Information

Additional information about the Gulf LNG Clean Energy Marine Terminal Project is available from FERC's Office of External Affairs at 1-866-208-FERC or on the FERC Internet Web site (<http://www.ferc.gov>) using their eLibrary link. Comments relating to aspects other than marine safety and security aspects associated with the proposed LNG facility may be submitted at this Web site. For assistance, please contact FERC online support at FERCOnlineSupport@ferc.gov or toll free at 1-866-208-3676, or for TTY contact 1-202-502-8659.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request assistance at the meeting, contact Lieutenant (Junior Grade) J. Mangum listed under **FOR FURTHER INFORMATION CONTACT** as soon as possible.

Dated: November 10, 2005.

Steve Venckus,

Chief, Office of Regulations and Administrative Law, Office of the Judge Advocate General, U.S. Coast Guard.

[FR Doc. 05-22828 Filed 11-14-05; 3:29 pm]

BILLING CODE 4910-15-U

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[COTP Mobile-05-050]

Notice, Request for Comments; Letter of Recommendation, LNG Bayou Casotte Energy LLC Terminal Project, Jackson County, MS

AGENCY: Coast Guard, DHS.

ACTION: Request for comments; notice of public meeting.

SUMMARY: In accordance with the requirements in 33 CFR 127.009, the U.S. Coast Guard Captain of the Port (COTP) Mobile, AL is preparing a letter of recommendation as to the suitability of the Pascagoula Bar, Horn Island Pass, Lower Pascagoula, and Bayou Casotte Channels for liquefied natural gas (LNG) marine traffic. The letter of recommendation is in response to a letter of intent submitted by Bayou Casotte Energy LLC to operate a LNG facility in Jackson County, MS. The COTP Mobile, AL is soliciting written comments and related material, and will hold a public meeting seeking comments, pertaining specifically to maritime safety and security aspects of the proposed LNG facilities. In preparation for issuance of a letter of recommendation and the completion of certain other regulatory mandates, the COTP Mobile, AL will consider comments received from the public as input into a formalized risk assessment process. This process will assess the safety and security aspects of the facility, adjacent port areas, and navigable waterways.

DATES: All written comments and related material must reach the Coast Guard on or before December 14, 2005. In addition, a public meeting will be held December 7, 2005 from 5 p.m. to 7 p.m. local time. Those who plan to speak at the meeting should provide their name by December 2, 2005 to Lieutenant (Junior Grade) J. Mangum using one of the methods listed under **FOR FURTHER INFORMATION CONTACT**. The comment period associated with the public meeting will remain open for seven days following the meeting. The meeting location is: Pascagoula High School, 1716 Tucker Ave, Pascagoula, MS.

ADDRESSES: You may submit written comments to Commanding Officer, U.S. Coast Guard Sector Mobile, Brookley Complex, Bldg 102, South Broad Street, Mobile, AL 36615-1390. Sector Mobile maintains a file for this notice. Comments and material received will

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- (1) Phone at 251-441-5940;
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SUPPLEMENTARY INFORMATION:

Request for Written Comments

We encourage you to submit written comments and related material pertaining specifically to marine safety and security aspects associated with the proposed LNG facilities. If you do so, please include your name and address, identify the docket number for this notice (COTP Mobile-05-050), and give the reason for each comment. You may submit your comments and related material by mail, or hand delivery, as described in **ADDRESSES**, or you may send them by fax or e-mail using the contact information under **FOR FURTHER INFORMATION CONTACT**. To avoid confusion and duplication, please submit your comments and material by only one means.

If you submit 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 U.S. Coast Guard Sector Mobile, please enclose a stamped, self-addressed postcard or envelope.

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