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]

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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