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 to CDER 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.

ADDITIONAL 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 CBER 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]

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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. (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.


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

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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...