

recordkeeping practices and falsified records it submitted to FDA. In support of the proposed revocation, FDA had placed documentation on file for public examination with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Following publication of the notice of opportunity for a hearing on July 10, 2003, FDA's Division of Dockets Management received a letter (via electronic transmission), dated August 11, 2003. In the letter, URI requested a hearing on the proposed license revocation and set forth information to support its request.

While the request for hearing was pending, the authorized official of the firm voluntarily requested revocation of U.S. License No. 0887 by letter dated December 29, 2003. FDA notified URI by letter of March 2, 2004, that the license had been revoked. Based on the voluntary request for revocation of U.S. License No. 0887, URI's request for a hearing on the issue of license revocation became unnecessary.

Accordingly, under § 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (FDA Staff Manual Guides (SMG) 1410.10) <http://www.fda.gov/smg/default.htm> and redelegated to the Director, Center for Biologics Evaluation and Research (SMG 1410.204), the biologics license (U.S. License No. 0887) for the manufacture of Source Plasma issued to URI was revoked, effective March 2, 2004.

This notice is issued and published under § 601.8 and the redelegation at SMG 1410.203.

Dated: November 29, 2004.

**Jesse Goodman,**

*Director, Center for Biologics Evaluation and Research.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[CGD08-04-044]

### Houston/Galveston Navigation Safety Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meetings.

**SUMMARY:** The Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) and its working groups will meet to discuss waterway

improvements, aids to navigation, area projects impacting safety on the Houston Ship Channel, and various other navigation safety matters in the Galveston Bay area. All meetings will be open to the public.

**DATES:** The next meeting of HOGANSAC will be held on Thursday, February 10, 2005 at 9 a.m. The meeting of the Committee's working groups will be held on Tuesday, January 18, 2005 at 9 a.m.

**ADDRESSES:** The full Committee meeting will be held at the Barbour's Cut Cruise Terminal, 820 North L Street, Morgan's Point, TX 77572, (281-470-1800). The working groups meeting will be held at the Port of Texas City office building, 2425 Highway 146 North, Texas City, TX 77552 (409-945-4461).

**FOR FURTHER INFORMATION CONTACT:**

Captain (CAPT) Richard Kaser, Executive Director of HOGANSAC, telephone (713) 671-5199, Commander (CDR) Tom Marian, Executive Secretary of HOGANSAC, telephone (713) 671-5164, or Lieutenant Junior (LTJG) Grade Brandon Finley, Assistant to the Executive Secretary of HOGANSAC, telephone (713) 671-5103, e-mail [rfinley@vtshouston.uscg.mil](mailto:rfinley@vtshouston.uscg.mil). Written materials and requests to make presentations should be sent to Commanding Officer, VTS Houston/Galveston, Attn: LTJG Finley, 9640 Clinton Drive, Floor 2, Houston, TX 77029.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

### Agenda of the Meetings

*Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC).* The tentative agenda includes the following:

(1) Opening remarks by the Committee Sponsor (RADM Duncan) or the Committee Sponsor's representative, Executive Director (CAPT Kaser) and Chairperson (Mr. Tim Leitzell).

(2) Approval of the October 5, 2004 minutes.

(3) Old Business:

(a) Dredging projects; (b) AtoN Knockdown Working Group; (c) Navigation Operations subcommittee report; (d) Education and Outreach subcommittee report; (e) Area Maritime Security Committee Liaison's report; (f) Technology subcommittee report; (g) Safe Harbor Working Group; (h) Deepdraft Entry Facilitation Working Group; (i) Galveston Causeway Construction Working Group.

(4) New Business: (a) State of the Waterway presentation; (b) Renewal of HOGANSAC charter (2004-2006); (c)

Recognition of new membership; (d) 2005 Harbor Safety Conference; (e) Public Service Awards.

*Working Groups Meeting.* The tentative agenda for the working groups meeting includes the following:

(1) Presentation by each working group of its accomplishments and plans for the future.

(2) Review and discuss the work completed by each working group.

### Procedural

Working groups have been formed to examine the following issues: Dredging and related issues, electronic navigation systems, AtoN knockdowns, impact of passing vessels on moored ships, boater education issues, facilitating deep draft movements and mooring infrastructure. Not all working groups will provide a report at this session. Further, working group reports may not necessarily include discussions on all issues within the particular working group's area of responsibility. All meetings are open to the public. Please note that the meetings may adjourn early if all business is finished. Members of the public may make presentations, oral or written, at either meeting. Requests to make oral or written presentations should reach the Coast Guard five (5) working days before the meeting at which the presentation will be made. If you would like to have written materials distributed to each member of the committee in advance of the meeting, you should send your request along with fifteen (15) copies of the materials to the Coast Guard at least ten (10) working days before the meeting at which the presentation will be made.

### Information on Services for the Handicapped

For information on facilities or services for the handicapped or to request special assistance at the meetings, contact the Executive Director, Executive Secretary, or Assistant to the Executive Secretary as soon as possible.

Dated: December 16, 2004.

**R.F. Duncan,**

*Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.*

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