presentations of the datasets for routine toxicology studies (e.g., chronic toxicology and carcinogenicity studies). Version 3.1 (V3.1) of the CDISC Submission Data Domain Standards was officially released on June 25, 2004. These standards and the accompanying Implementation Guide can be viewed on the CDISC Web site at *www.cdisc.org*.[1]

FDA has performed some initial pilot testing of nonclinical and clinical data applicable to drugs. The purpose of this pilot project is to evaluate the Version 3.1 of the CDISC SDTM and the Implementation Guide to determine applicability to clinical and nonclinical data required for submission of CBER regulated BLAs, to help in the refinement of analysis tools designed to facilitate the review and evaluation of electronic nonclinical and clinical datasets, and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized nonclinical and clinical data and metadata in a format that is applicable to BLA submissions.

II. Pilot Project Description

This pilot project is part of an effort to improve the process for submitting nonclinical and clinical data. Eventually, FDA expects to recommend detailed data standards for the submission of nonclinical and clinical data. Participants in this pilot project will have the opportunity not only to assist the agency in testing the use of various analysis tools and standardized nonclinical and clinical data and metadata, but would also be able to familiarize themselves with the process at an early stage of development. Only a few participants are needed for this pilot.

A. Initial Approach

Because a limited group of voluntary participants are needed, the agency will use its discretion in choosing volunteers, based on their having previously submitted nonclinical and clinical datasets to FDA and having demonstrated familiarity with our recommendations for creating nonclinical and clinical datasets as presented in the ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications.'' During the pilot project, specific technical instructions for providing the nonclinical and clinical data for testing will be made available to pilot participants. Participants in the pilot project will be asked to provide nonclinical and clinical datasets as described in the technical instructions and to provide technical feedback.

B. Scope

Existing requirements for the submission of CBER nonclinical and clinical data will not be waived, suspended, or modified for purposes of this pilot project. The pilot project will test the preparation and use of the submitted nonclinical and clinical electronic datasets.

C. How to Participate

Written requests to volunteer should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. We will consider all received comments in making a determination on electronic filing and when drafting a guidance document for submitting CBER nonclinical and clinical study data as electronic datasets. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28579 Filed 12–29–04; 8:45 am]

BILLING CODE 4160–01–S

[1]FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0232]

Universal Reagents, Inc.; Revocation of U.S. License No. 0887

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 0887) issued to Universal Reagents, Inc., (URI) for the manufacture of Source Plasma. A notice of opportunity for a hearing on a proposal to revoke the license was published in the **Federal Register** of July 10, 2003. URI requested a hearing by letter dated August 11, 2003. Subsequently, the authorized official of URI voluntarily requested revocation of its biologics license (U.S. License No. 0887) by letter dated December 29, 2003. In light of URI's request for revocation of its license, the firm's request for an opportunity for a hearing on the issue of license revocation became unnecessary. FDA, therefore, proceeded to revoke the license.

DATES: The revocation of U.S. License No. 0887 became effective March 2, 2004.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has revoked the biologics license (U.S. License No. 0887) for the manufacture of Source Plasma issued to URI, 2858 North Pennsylvania St., Indianapolis, IN 46205.

By certified return receipt letter, dated October 23, 2002, issued under § 601.5(b) (21 CFR 601.5(b)), FDA notified the firm of FDA's intent to revoke U.S. License No. 0887 and announced its intent to offer an opportunity for a hearing. Because URI did not submit a response to FDA's letter dated October 23, 2002, and did not waive an opportunity for hearing under 21 CFR 12.21(b), FDA issued a notice of opportunity for a hearing in the **Federal Register** of July 10, 2003 (68 FR 41162), on the proposal to revoke the biologics license (U.S. License No. 0887) issued to URI for the manufacture of Source Plasma. As described in the notice of opportunity for a hearing, the grounds for the proposed license revocation included the following: (1) The results of an FDA inspection of the firm conducted between May 29 and June 3, 2002; as well as from the inspection on June 7, 2002, of Central Indiana Regional Blood Center, Inc. (CIRBC), Indianapolis, IN, which performed infectious disease testing for URI under a contract agreement; (2) FDA's determination through its investigation and inspections of both URI and CIRBC, that URI had significant deviations from the standards established in its license as well as in the applicable Federal regulations; and (3) documentation that URI had willfully engaged in violative

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.

[FR Doc. 04–28580 Filed 12–29–04; 8:45 am]

BILLING CODE 4160–01–S

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*. 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.

[FR Doc. 04–28551 Filed 12–29–04; 8:45 am]

BILLING CODE 4910–15–P