III. Registration Instructions

The Division of Acute Care is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Individuals may present their comments either in person or by phone. These individuals must register and submit their agenda item(s) by February 15, 2005. All other participants must register by February 17, 2005. All registrants will receive confirmation with instructions for arrival at the CMS complex (persons who register on-line will receive this confirmation upon completion of the registration process and should print the confirmation and bring it with them to the meeting). Because of limited meeting space and our desire to maintain an accurate count of registrants that plan to come to CMS, we prefer that these persons register on-line. In addition, we would prefer that registrants that plan to participate by phone, register by phone or fax.

On-line Registration: Registration may be completed on-line at the following web address: *http://www.cms.hhs.gov/providers/hipps/newtech.asp.* Select the link ''Register to Attend the New Technology Town Hall Meeting'' and then select ''New Technology Town Hall Meeting'' from the drop down menu and follow the instructions. After completing registration, on-line registrants should print the confirmation page and bring it with them to the meeting.

Registration by Phone or Fax: Registration may be completed by contacting Meredith Walz at (410) 786–9421 or Michael Treitel at (410) 786–4552. Registration may also be completed by fax to the attention of Meredith Walz or Michael Treitel at (410) 786–0169. If registration is completed by phone or fax, please provide your name, address, telephone number, and, if available, e-mail address and fax number.

IV. Security Information

Since this meeting will be held in a Federal government building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of their confirmation of registration for the meeting. Access may be denied to persons without proper identification. For security reasons, no additional meeting registrations will be accepted after the close of the registration period.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. Laptops and other computer equipment must be registered with the security desk upon entry. CMS cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Participants should e-mail presentations to CMS prior to the meeting to ensure that CMS has a back-up copy in the event of computer problems or lack of software or memory card compatibility. Please note that CMS headquarters is a smoke-free facility.

Authority: Section 503 of Public Law 108–173.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 16, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–28153 Filed 12–29–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0545]

Nonclinical and Clinical Datasets; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is seeking volunteers to participate in a pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal and human data submitted to FDA by applicants of biologics license applications (BLAs). These analysis tools will allow a reviewer to more efficiently capture and evaluate nonclinical and clinical datasets submitted in electronic format.

DATES: Submit written requests to participate in the pilot project by February 28, 2005. Comments on this pilot project may be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding the pilot project to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Richard Diamond, Center for Biologics Evaluation and Research (HFM–6), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0372.

SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA regulations (21 CFR 601.2), applicants must provide nonclinical and clinical data in BLAs. CBER provided recommendations for the electronic submission of BLAs, as well as new drug applications (NDAs), in the ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications'' dated November 1999. A joint CBER and Center for Drug Evaluation and Research (CDER) document entitled ''Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations'' dated January 1999 provided recommendations for the file formats for nonclinical and clinical datasets.

FDA announced on July 21, 2004, a standard format, called the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium (CDISC), that sponsors of human drug clinical trials can use to submit data to the agency. It is expected that this step will lead to greater efficiencies in clinical research and FDA reviews of NDAs and BLAs. CDISC is an open, multidisciplinary, nonprofit organization including members from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors. CDISC committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. CDISC is currently facilitating the work on similar standards for nonclinical and clinical datasets. Where possible, the standards developed for clinical datasets and metadata should be used in the development of standardized

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