

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0232]

Universal Reagents, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 0887

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for hearing on a proposal to revoke the biologics license (U.S. License No. 0887) issued to Universal Reagents, Inc. (URI), for the manufacture of Source Plasma. The proposed revocation is based on the failure of the establishment and the product for which the license has been issued to conform to the applicable standards established in the license and in the regulations.

DATES: URI may submit a written or electronic request for a hearing to the Division of Dockets Management by *[insert date 30 days after date of publication in the **Federal Register**]*, and any data and information justifying a hearing by *[insert date 60 days after date of publication in the **Federal Register**]*. Other interested persons may submit written or electronic comments on the proposed revocation to the Division of Dockets Management by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests or comments to <http://www.fda.gov/dockets/ecomments>.

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

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the biologics license (U.S. License No. 0887) issued to URI, 2858 North Pennsylvania St., Indianapolis, IN 46202, for the manufacture of Source Plasma. The proposed revocation is based on the failure of URI to conform to the applicable standards established in its license and certain requirements of subchapter F, parts 600 to 640 (21 CFR parts 600 to 640).

I. Findings

FDA inspected URI between May 29 and June 3, 2002. Additionally, on June 7, 2002, FDA inspected Central Indiana Regional Blood Center, Inc. (CIRBC), Indianapolis, IN, which performs infectious disease testing for URI under a contract agreement. FDA determined, 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. FDA also documented that URI has willfully engaged in violative recordkeeping practices and falsified records it submitted to FDA. The deviations noted during the inspections included, but were not limited to, the following:

1. In violation of §§ 610.40(a) and 606.160(b)(2)(i), test results for Source Plasma units 0730900, 0730911, and 0730912 for the hepatitis B surface antigen (HBsAg) and the antibody to the human immunodeficiency virus types 1 and 2 (anti-HIV-1/2) were missing from the Transfer PC Mainframe Unit

Rejection Report (a computer generated report). On June 3, 2002, URI provided the FDA investigator with what URI identified as the missing test results.

According to these results, the HBsAg and anti-HIV-1/2 tests, which purportedly were performed by CIRBC, were negative for Source Plasma units 0730900, 0730911, and 0730912. However, the document did not bear a date or time in the designated reporting fields. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that the required testing for HBsAg and anti-HIV-1/2 was not completed or performed for these Source Plasma units.

2. In violation of §§ 610.40(a) and 606.160(b)(2)(i), HBsAg and anti-HIV-1/2 test results for Source Plasma unit 0729859 were missing on a Transfer Report and on a Testing Status Report. An additional notation on the Testing Status Report stated "sample too old to complete testing." An additional record that FDA collected during the URI inspection, a Laboratory Request Form dated June 4, 2001, that URI generated, showed that all test results for unit 0729859, including HBsAg and anti-HIV-1/2 testing, were documented as "NR" or nonreactive. During the closeout discussion on June 3, 2002, URI provided the FDA investigator with a Testing Status Report stating that the testing had been performed at CIRBC and that test results for HBsAg and anti-HIV-1/2 were "N" or negative for unit 0729859. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that infectious disease testing for HBsAg and anti-HIV-1/2 was not performed on Source Plasma unit 0729859.

3. In violation of § 606.160(b)(2)(i), URI failed to maintain anti-HIV-1/2 re-testing results for Source Plasma unit 0729718. On a Transfer Report dated May 5, 2001, Source Plasma unit 0729718 tested reactive for anti-HIV-1/2 in

testing conducted by CIRBC. Rather than producing the results of re-testing on that unit, however, URI provided the FDA investigator, during the closeout discussion on June 3, 2002, with a Testing Status Report for unit 0729718 that noted an “N” or “nonreactive” test result for the initial anti-HIV-1/2 test. No date or time was documented on the report; however, a notation on the report stated that it was reviewed by URI on May 9, 2000 [sic]. The sequence number noted on the report was 7899. FDA’s inspection of CIRBC disclosed that all infectious disease testing related to anti-HIV-1/2 that CIRBC performed on unit 0729718 in 2001 was associated with sequence number 1995, not 7899. CIRBC’s records showed that anti-HIV-1/2 testing for unit 0729718 was performed on or about May 5, 2001, and the result was reactive. CIRBC’s records showed that the results of repeat duplicate anti-HIV-1/2 tests on unit 0729718, conducted on May 7, 2001, were negative.

In a certified, return-receipt letter dated October 23, 2002, and issued under § 601.5(b), FDA outlined the deviations noted at the inspection of URI. FDA notified URI of FDA’s intent to revoke U.S. License No. 0887 and announced the agency’s intent to offer an opportunity for hearing. In situations involving willfulness, FDA need not provide an opportunity for the licensee to demonstrate or achieve compliance. FDA acknowledged receipt of URI’s June 7, 2002, response to the Form FDA-483 for the May 29 to June 3, 2002, inspection to which URI had attached copies of the same falsified and discrepant records that URI previously provided to the FDA investigator during the inspection. FDA’s review of the response disclosed continuing inconsistencies with the results of the inspection and investigation.

Based on FDA’s inspectional and investigational results, FDA has determined that URI willfully engaged in violative recordkeeping practices and

provided false manufacturing records to FDA as corrective actions for the previously noted deficiencies. Additionally, URI's June 7, 2002, response to the Form FDA-483 demonstrates that URI willfully continued to submit falsified documents to FDA.

FDA also notes that URI has had a history of noncompliance with the applicable standards and regulations as shown by significant deviations that were documented during previous inspections of URI. Among those various deviations were discrepancies in URI's test result records, including discrepancies in the test results for the antibody to HIV type 1. FDA emphasized the seriousness of URI's various deviations in letters to URI, including a notice of adverse findings letter dated October 20, 1988, a notice of adverse findings letter dated September 26, 1989, a warning letter dated October 19, 1992, and a warning letter dated July 20, 2000.

II. Notice of Opportunity for Hearing

Because URI did not submit a response to the FDA letter dated October 23, 2002, and did not waive an opportunity for hearing under 21 CFR 12.21(b), FDA is issuing a notice of opportunity for hearing on a proposal to revoke the biologics license (U.S. License No. 0887) issued to URI for Source Plasma.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. These documents include FDA's letters to URI dated October 20, 1988, September 26, 1989, October 19, 1992, July 20, 2000, and October 23, 2002, and URI's response to FDA dated June 7, 2002. These documents are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on a proposed revocation of a license are contained in parts 601 and 12 (21 CFR part 12). In requesting a hearing, a person must submit to FDA's Division of Dockets Management objections and a request for a hearing on each objection, along with a detailed description and analysis of the factual information to be presented in support of each objection, as provided in § 12.22. A deficient request or objection will be returned; however, the deficient submission may be supplemented and subsequently filed if submitted within the 30-day time period (§ 12.22(c)). The objections should identify the specific fact or facts that are genuine, substantial, and in dispute (§ 12.24(b)(1)). Mere allegations or denials are not enough to obtain a hearing (§ 12.24(b)(2)). The Commissioner of Food and Drugs (the Commissioner) will deny the hearing request if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)).

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be examined in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, 701 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under authority delegated to the Commissioner (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.202).

Dated: June 30, 2003.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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