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. 03–17410 Filed 7–9–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Application Cycle for the Nursing Scholarship Program CFDA 93.908

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of time for application deadline.

SUMMARY: This notice extends the time that applications will be accepted for fiscal year 2003 for the Nursing Scholarship Program. A May 6, 2003 **Federal Register** Notice (68 FR 24006) announced that applications for the Nursing Scholarship Program must be received, or postmarked, on or before June 30, 2003. For individuals who requested a Nursing Scholarship Program application before June 30, 2003, the deadline for receipt of an application has been extended to July 14, 2003. These applications must be received by the Nursing Scholarship Program, c/o I.Q. Solutions, 11300 Rockville Pike, Suite 801, Rockville, Maryland 20852, on or before July 14, 2003.

FOR FURTHER INFORMATION CONTACT: Capt. Bruce Baggett, Division of National Health Service Corps, Bureau of Health Professions, Room 8A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; 1–800–435–6464 (*bbaggett@hrsa.gov*).

Dated: July 7, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–17587 Filed 7–8–03; 11:59 am]

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