Services, Lubbock, TX, from March 16 through March 25, 1994. The inspection also involved a concurrent investigation which included interviews with individuals knowledgeable about the firm's operations. The inspection and the investigation documented serious deviations from the applicable Federal regulations. Deviations identified in the inspection included, but were not limited to, the following: (1) Failure to collect blood by aseptic methods in a sterile system to protect against contamination (21 CFR 640.4(f)), in that: (a) current and former employees stated in affidavits that on numerous occasions employees broke the sterility barrier of blood containers and drained blood into vacutainer tubes or biohazard containers in order to conceal overbleeds, and (b) employees used an incorrect phlebotomy technique on numerous occasions thereby possibly contaminating the blood collection bags with room air; (2) failure to maintain records of donor adverse reaction reports (21 CFR 606.160(b)(1)(iii)), in that, on numerous occasions, employees did not document mild to moderate donor adverse reactions; (3) failure to follow standard operating procedures to adequately determine donor suitability (21 CFR 606.100(b)(1)), in that employees stated that: (a) donors were not always asked screening questions, such as high risk behavior questions, in order to expedite the donation process, (b) donors were sometimes asked if anything had changed since the last time they donated instead of being asked the required acquired immune deficiency syndrome (AIDS)-related behavior questions, and (c) individuals under the influence of alcohol were accepted as blood donors; and (4) failure to adequately and promptly notify the Director, Center for Biologics Evaluation and Research, of such errors or accidents in the manufacture of products that may affect the safety, purity or potency of any product pursuant to 21 CFR 600.14, in that, all known facts of the incidents involving a phlebotomist who used an incorrect phlebotomy technique, whereby the units may have become contaminated with room air, were not reported to the agency.

FDA determined that the deviations from Federal regulations were significant and constituted a danger to public health, warranting a suspension pursuant to 21 CFR 601.6(a). In a letter to Blood Systems, Inc., United Blood Services, dated June 6, 1994, FDA detailed the violations noted earlier in this document and suspended the firm's establishment and product licenses. In the same letter, FDA acknowledged receipt of letters dated April 13, April 15, and May 24, 1994, submitted by the firm in response to the Form FDA–483, Inspectional Observations, left at the close of the inspection. FDA concluded that the firm's promises of corrective action were not sufficient based on the seriousness of the documented deviations. It was FDA's view that the establishment and products failed to conform to applicable donor protection standards which are intended to ensure a continuous and healthy donor population, as well as standards designed to ensure the continued safety, purity, potency, and quality of products manufactured.

FDA's letter dated June 6, 1994, also stated that the agency's inspection and investigational findings, including evidence that records were knowingly falsified, demonstrated willfulness on the part of the firm. As a result, pursuant to 21 CFR 601.5(b) the firm was not given additional time to achieve compliance with the regulations. The same letter provided notice that FDA intended to initiate proceedings to revoke U.S. License No. 183–009 and product licenses issued to Blood Systems, Inc., United Blood Services pursuant to 21 CFR 601.5(b) and provided notice of opportunity for a hearing pursuant to 21 CFR 12.21(b). In a letter to FDA dated June 8, 1994, Blood Systems, Inc., voluntarily requested that its licenses for the Lubbock, TX, location be revoked and thereby waived its opportunity for a hearing. In a letter to the firm dated July 13, 1994, FDA acknowledged voluntary revocation of the establishment license (U.S. License No. 183–009) and the aforementioned product licenses of Blood Systems, Inc., United Blood Services at the Lubbock, TX, location only. In the July 13, 1994, letter to the firm, FDA restricted the interstate distribution of autologous units currently in inventory except in documented emergency situations, and permitted the firm to resume collections of allogeneic and autologous blood products intended for distribution within the State of Texas.

FDA has placed copies of letters relevant to the license revocations on file under the docket number found in brackets in the heading of this document in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under section 351 of the Public Health Act (42 U.S.C. 262), 21 CFR 601.5, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 183–009) and the product licenses issued to the Lubbock, TX, location of Blood Systems, Inc., United Blood Services for the manufacture of Whole Blood, Red Blood Cells, Plasma, Cryoprecipitated AHF, Platelets, and Source Leukocytes, were revoked, effective July 19, 1994.

This notice is issued and published under 21 CFR 601.8 and under authority delegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: October 31, 1995.

Michael G. Beatrice,

Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 95–29220 Filed 11–29–95; 8:45 am]

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Health Resources and Services Administration

Advisory Council on Nurses Education; Notice of Meeting Cancellation

In Federal Register Document 95–27189 appearing on page 55720 in the issue for Tuesday, November 2, 1995, the December 14–15, 1995, meeting of the ''National Advisory Council on Nurse Education and Practice'' will be cancelled.

Dated: November 27, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 95–29260 Filed 11–29–95; 8:45 am]

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National Institutes of Health

National Institutes of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of the rescheduling of the meeting of the Environmental Health Sciences Review Committee, the notice of which was published in the Federal Register 60 FR 49848 on September 27, 1995. This meeting could not be convened on November 16–17 due to the partial shutdown of the Federal Government. it is rescheduled for December 3–5 at 6:00 p.m., at the Omni Europa Hotel, Chapel Hill, NC, and is closed to members of