

the proposed revocation action. BCI did not submit, within the 30-day time period, a written request for a hearing on the proposed revocation of its license. The 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulations, may not be extended. No other written comments on the proposed revocation were received within the prescribed 60 days specified in the notice of opportunity for a hearing.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), 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 5.67), U.S. License No. 1160, issued to Bio-Components, Inc., is revoked effective August 5, 1997.

This notice is issued and published under 21 CFR 601.8.

Dated: July 28, 1997.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0015]

Personal Blood Storage of Memphis, Inc.; Revocation of U.S. License No. 1131

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1131) and the product licenses issued to Personal Blood Storage of Memphis, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Platelets. Personal Blood Storage of Memphis, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of the establishment license (U.S. License No. 1131) and the product licenses is effective August 5, 1997.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 1131) and the product licenses issued to Personal Blood Storage of Memphis, Inc., formerly located at 5182 East Raines Rd., Memphis, TN 38118, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Platelets.

An attempted onsite inspection by FDA on May 23, 1995, revealed that the facility was no longer in operation at the location listed on the license. An FDA investigator, from the Nashville District Office, was permitted to visit the unoccupied facility on August 3, 1995. The investigator documented that the office space and two walk-in freezers were empty and there was no electrical or water service at the facility. Based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility, FDA initiated proceedings for the revocation of the licenses under 21 CFR 601.5(b)(1) and (b)(2). The U.S. Postal Service supplied FDA with the firm's forwarding address, and FDA sent a certified letter, dated September 8, 1995, to the firm's responsible head providing notice of FDA's intent to revoke the licenses and its intent to offer an opportunity for a hearing on the proposed revocation. The responsible head responded by telephone on September 12, 1995, and said that she was no longer employed by Personal Blood Storage of Memphis, Inc. She also sent a copy of a March 3, 1995, letter to the Center for Biologics Evaluation and Research (CBER), in which she stated that she was no longer the technical director or responsible head for Personal Blood Storage of Memphis, Inc. A copy of FDA's letter of intent to revoke U.S. License No. 1131 was also sent to one owner's address in Texas and this letter was returned by the U.S. Postal Service as unclaimed.

Under § 12.21(b) (21 CFR 12.21(b)), FDA published in the **Federal Register** of April 24, 1996 (61 FR 18149), a notice of opportunity for a hearing on a proposal to revoke the licenses of Personal Blood Storage of Memphis, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation and noted that documentation in support of the license revocation had been placed on file for public examination with the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data

and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. Under § 12.21(b), the 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulations, may not be extended. No other interested persons submitted written comments on the proposed revocation within the 60-day time period.

Accordingly, under 21 CFR 12.38(a)(1), section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, CBER (21 CFR 5.67), the establishment license (U.S. License No. 1131), and the product licenses issued to Personal Blood Storage of Memphis, Inc., are revoked, effective August 5, 1997.

This notice is issued and published under 21 CFR 601.8.

Dated: July 28, 1997.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: To evaluate research grant R03 AI41597-01 (Telephone Conference Call).

Date: August 11, 1997.

Time: 1:00 p.m. to Adjournment.

Place: Teleconference, 6003 Executive Boulevard, Solar Bldg., Room 4C01, Bethesda, MD 20892, (301) 496-2550.

Contact Person: Dr. Kevin Callahan, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C20, Bethesda, Md 20892, (301) 496-8424.

Purpose/Agenda: To evaluate a grant application.

This meeting will be closed in accordance with the provisions set forth in sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S.C. Applications and/or proposals and the