establishments. There are an estimated 3,021 FDA registered blood collection facilities in the United States that annually collect an estimated 23,500,000 units of whole blood and source plasma. Of the 3,021 registered establishments, 1,799 establishments perform pheresis collections and 278 establishments perform transfusions. There are also an estimated 4,500 Health Care Financing Administration registered transfusion services. The recordkeeping chart reflects the estimate that 95 percent of the recordkeepers which collect 98 percent of the blood supply had developed SOP's as part of their normal business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOP's developed by blood organizations. These blood organizations represent almost all of the registered establishments.

FDA estimates the burden of this information collection as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)	42	1	42	8	336

There are no capital costs or operating and maintenance costs associated with this information collection.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)	151	1	151	24	3,624
606.100(c)	151	3.6	550	3.6	550
606.110(a)	90	5	450	2.5	225
606.151(e)	239	12	2,868	1	239
606.160	151	3,112	470,000	1,556	234,956
606.165	151	3,112	470,000	258	38,958
606.170(a)	376	12	4,512	12	4,512

There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: July 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20495 Filed 8-4-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0155]

Bio-Components, Inc.; Revocation of U.S. License No. 1160

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of U.S. License No. 1160, which includes the establishment license and the product licenses for the manufacture of Source Plasma and Source Leukocytes, issued to Bio-Components, Inc. (BCI). BCI did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of U.S. License No. 1160 is effective August 5, 1997.

FOR FURTHER INFORMATION CONTACT: Annette A. Ragosta, 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. 1160) and the product licenses issued to Bio-Components, Inc., 440 North Beach St., Daytona Beach, FL 32114, for the manufacture of Source Plasma and Source Leukocytes. The revocation is based on the failure of BCI, and its responsible management to conform to the applicable standards established in the license and to the applicable Federal regulations designed to ensure the continued safety, purity, and potency of the manufactured product (see § 601.5(b)(4) (21 CFR 601.5(b)(4))).

In a letter dated May 13, 1994, FDA informed BCI of the agency's intent to revoke the firm's license and its intent to issue an opportunity for a hearing on the proposed revocation. In the **Federal Register** of January 30, 1996 (61 FR 3040), FDA published a notice of opportunity for a hearing on the proposed revocation of the license under § 12.21(b) (21 CFR 12.21(b)), as provided in § 601.5(b). As described in the notice of opportunity for a hearing, the grounds for the proposed license revocation were based on the results of an FDA inspection of BCI conducted between January 21, 1993, and February 12, 1993. FDA determined that the deviations documented during the January and February 1993 inspection constituted a danger to the public health and accordingly suspended BCI's license in a letter dated March 19, 1993. FDA subsequently determined that BCI demonstrated careless disregard for the applicable regulations and the applicable standards in its license due to, among other things, the firm's past history of noncompliance and the firm's failure to submit an adequate corrective action plan. Due to this evidence of willfulness, FDA did not provide BCI with further opportunity to demonstrate or achieve compliance. Documentation in support of the proposed 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 of opportunity for a hearing provided BCI with 30 days to submit a written request for a hearing, as specified in § 12.21(b), and 60 days to submit any data or information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on

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.

[FR Doc. 97–20496 Filed 8-4-97; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 97–20494 Filed 8-4-97; 8:45 am]

BILLING CODE 4160–01–F

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 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the