dealing in, to a limited extent, all types of debt and equity securities, other than interests in open end investment companies; *See J.P. Morgan & Co., Inc., et al., 75 Fed. Res. Bull. 192 (1989) and Citicorp, et al., 73 Fed. Res. Bull. 473 (1987)*; underwriting and dealing in bank-eligible securities, pursuant to § 225.28(b)(8) of the Board's Regulation Y; providing securities brokerage services on either a stand-alone or full-service basis, pursuant to § 225.28(b)(7) of the Board's Regulation Y; acting as agent for issuers and holders in the private placement of various types of securities with financially sophisticated counterparties in a non-public offering, pursuant to § 225.28(b)(7) of the Board's Regulation Y; buying and selling on the order of investors as a riskless principal, pursuant to § 225.28(b)(7) of the Board's Regulation Y; making, acquiring or servicing loans or other extensions of credit, including purchasing and selling such loans and extensions of credit in the secondary market, and engaging in mortgage banking activities, pursuant to § 225.28(b)(1) of the Board's Regulation Y; acting as an investment or financial advisor to the extent of (i) serving as the advisory company for a mortgage or real estate investment trust; (ii) serving as an investment adviser to an investment company registered under the 1940 Act, including sponsoring, organizing and managing a closed-end investment company; (iii) providing portfolio investment advice; (iv) furnishing general economic information and advice, general economic statistical forecasting services and industry studies; and/or (v) providing financial advice to state and local governments, such as with respect to the issuance of their securities, pursuant to § 225.28(b)(6) of the Board's Regulation Y; providing advice and acting as arranger in connection with merger, acquisition, divestiture and financial transactions, including public and private financings, loan syndications, interest rate and currency swaps, interest rate caps and similar transactions and/or furnishing evaluation and fairness opinions in connection with merger, acquisition, and similar transactions, pursuant to §§ 225.28(b)(6) and (b)(7) of the Board's Regulation Y; acting as agent or broker with respect to interests in loan syndications, interest rate and currency swaps, interest rate caps, floors and collars, and options on such instruments, pursuant to § 225.28(b)(7) of the Board's Regulation Y; leasing personal or real property or acting as agent, broker or adviser in leasing such property, pursuant to § 225.28(b)(3) of the Board's Regulation Y; providing management consulting advice to non-affiliated depository institutions, pursuant to § 225.28(b)(9) of the Board's Regulation Y; engaging in futures, forward and option contracts on bank-eligible securities for hedging purposes, pursuant to § 225.28(b)(8) of the Board's Regulation Y; engaging in securities credit activities, pursuant to the Federal Reserve's Regulation T (covering credit by brokers and dealers), including acting as a ''conduit'' or ''intermediary'' in securities borrowing and lending, pursuant to § 225.28(b)(7) of the Board's Regulation Y; and serving as the general partner of and holding equity interests in certain limited partnerships that would be exempt from registration under the 1940 Act, *See Meridian Bancorp, Inc., 80 Fed. Res. Bull. 736 (1994)*.

B. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. C B & T, Inc., McMinnville, Tennessee; to acquire CBT Insurance, Inc., Smithville, Tennessee, and thereby continue to engage in insurance activities, pursuant to § 225.28(b)(11) of the Board's Regulation Y. The proposed activity will be conducted throughout the state of Tennessee.

Board of Governors of the Federal Reserve System, July 31, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–20584 Filed 8-4-97; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects 1. Voluntary Industry ''Partner'' Survey to Implement Executive Order 12862—The Department of Health and Human Services plans to conduct mail surveys of its contractors in each agency to obtain feedback for improving acquisition products and services—Respondents: Contractors of the Department; Annual Responses: 2400; Average Burden per Response: 12 minutes; Total Annual Burden: 480 hours

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, S.W., Washington, DC, 20201. Written comments should be received within 60 days of this notice.

Dated: July 30, 1997.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 97–20569 Filed 8–4–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0311]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to the regulation of FDA's current good manufacturing practice

(CGMP) and related regulations for blood and blood components.

DATES: Submit written comments on the collection of information by October 6, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

CGMP and Related Regulations for Blood and Blood Components—Parts 606 and 640 (21 CFR Parts 606 and 640)—(OMB Control Number 0910–0116)—Reinstatement

Under the statutory requirements contained in the Public Health Service Act (42 U.S.C. 262), no blood, blood component, or derivative may move in interstate commerce unless: (1) It is propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license; (2) the product complies with regulatory standards designed to ensure safety, purity, and potency; and (3) it bears a label plainly marked with the product's proper name, its manufacturer, and expiration date.

The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventative and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

Section 606.100(b) requires that written standard operating procedures (SOP's) be maintained for the collection, processing, compatibility testing, storage and distribution of blood and blood components used for transfusion and manufacturing purposes. Section 606.100(c) requires the review of all pertinent records to a lot or unit of blood prior to release of the lot or unit. Any unexplained discrepancy or failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded. Section 606.110(a) requires a physician to certify in writing that the donor's health permits plateletpheresis or leukapheresis if a variance from additional regulatory standards for a specific product is used when obtaining the product from a specific donor for a specific recipient. Section 606.151(e) requires that records of expedited transfusions in life-threatening emergencies be maintained. So that all steps in the collection, processing, compatibility testing, storage and distribution, quality control, and transfusion reaction reports and complaints for each unit of blood and blood components can be clearly traced, § 606.160 requires that legible and indelible contemporaneous records of each significant step be made and maintained for no less than 5 years. Section 606.165 requires that distribution and receipt records be maintained to facilitate recalls, if necessary. Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. Section 606.170(b) requires that fatal complications of blood collections and transfusions be reported to FDA as soon as possible and that a written report shall be submitted within 7 days. In addition to the CGMP's in part 606, there are regulations in part 640 that require additional standards for blood and blood components: §§ 640.3(a) and (f), 640.4(a), 640.25(b)(4) and (c)(1), 640.27(b), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1) and (e)(3), 640.65(b)(2), 640.66, 640.71(b)(1), 640.72, 640.73, and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described below.

The recordkeeping requirements for §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOP's, are included in the estimate for § 606.100(b); the recordkeeping requirements for § 640.27(b), which addresses the maintenance of donor health records for plateletpheresis, is included in the estimate for § 606.110(a); and the recordkeeping requirements for §§ 640.3(a)(2), 640.3(f), 640.4(a)(2), 640.25(b)(4) and (c)(1), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1), and (e)(3), 640.65(b)(2), 640.71(b)(1), 640.72, and 640.76(a) and (b), which address the maintenance of various records, are included in the estimate for § 606.160. The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

Respondents to this collection of information are registered blood

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