concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 13, 1996.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. First Bankshares of Las Animan, Inc., Las Animan, Colorado; to engage *de novo* through its subsidiary, Sunshine Village Apartments of Las Animas, LTD, Las Animas, Colorado, in the construction of 24-unit senior and multi-family housing project, and thereby engage in community deveopment activities, pursuant to § 225.25(b)(6) of the Board's Regulation Y. The geographic scope for these activities is Las Animas, Colorado.

Board of Governors of the Federal Reserve System, January 24, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–1648 Filed 1–29–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

The Department of Health and Human Services, Office of the Secretary periodically publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Application for Correction of Public Health Service Commissioned Corps Records—0937–0095—Reinstatement No Change—An application is submitted by present and former PHS Commissioned Corps officers to request correction of an error or alleged injustice in their personnel records.

The information submitted is used by the Board for Correction to determine if an error or injustice has occurred and to rectify such error or injustice.

Respondents: Individuals; Annual Number of Respondents: 8;

Average Burden per Response: four hours; Frequency of response: single-time; Total Burden: 32 hours.

2. State Medicaid Fraud Control Units Annual Report and Certification Application (42 CFR 1007.15 and 1007.17)—0990–0162—Reinstatement No Change—The program data required of initial applicants to become certified, and the annual reports required for recertification are used by the Office of Inspector General to ensure that Federal matching funds are only expended for allowable costs. In addition, the reports are analyzed to monitor program activities and determine whether technical assistance is required.

Respondents: States; Burden Information for New Applicants—Number of Respondents: 2; Frequency of Response: one-time; Burden per Response: 112 hours; Burden for New Applicants: 224 hours—Burden Information for Recertification—Number of Respondents: 45; Frequency of Response: annually; Burden per Response: 56 hours; Burden for Recertification: 2520 hours—Total Burden: 2744 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 619–1053. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, D.C. 20503.

Dated: January 18, 1996.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 96–1633 Filed 1–29–96; 8:45 am]

BILLING CODE 4150–04–M

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the Federal Register.

The Secretary of the Treasury has certified a rate of 13¾% for the quarter ended December 31, 1995. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: January 22, 1996.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 96–1632 Filed 1–29–96; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 95N–0155]

Bio-Components, Inc.; Opportunity for a Hearing on a Proposal to Revoke U.S. License No. 1160

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 1160) and the product licenses issued to Bio-Components Inc. (BCI), for the manufacture of Source Plasma and Source Leukocytes. The proposed revocation is based on the firm's significant and continued noncompliance with Federal biologics regulations and standards included in the firm's license.

DATES: The firm may submit a written request for a hearing to the Dockets Management Branch by February 29, 1996, and any data and information justifying a hearing by April 1, 1996. Other interested persons may submit written comments on the proposed revocation by April 1, 1996

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635),

Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is proposing to revoke 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 proposed revocation is based on the failure of BCI, and its responsible management to conform to the Federal regulations applicable to the manufacture of biological products.

FDA conducted an inspection of BCI between January 21, 1993, and February 12, 1993. The inspection revealed deviations from the Federal regulations in 21 CFR parts 600 through 640 and from the applicable standards in the firm's license. FDA determined that these deviations constituted a danger to public health. The deviations were listed in a March 19, 1993, letter, from FDA to BCI which suspended the establishment license (U.S. License No. 1160) and the product licenses for the manufacture of Source Plasma and Source Leukocytes. The deviations included, but were not limited to, the failure to assure that: (1) Each donor's clinical post-immunization response to stimulation red blood cells was evaluated by a qualified physician (21 CFR 640.66); (2) serum protein electrophoresis (SPE) and a serologic test for syphilis were performed on each donor at least every 4 months (21 CFR 640.65(b)(1)(i)); (3) a qualified physician approved the plasmapheresis procedures of any donor whose SPE or rapid plasma reagin (RPR) test sample had not been collected at the required 4-month interval (21 CFR 640.65(b)(1)(ii)); (4) SPE results were reviewed by a qualified physician within 21 days after the sample was drawn to determine whether or not the donor may continue in the program (21 CFR 640.65(b)(2)(i)); (5) personnel had the capabilities commensurate with their assigned functions (21 CFR 600.10(b) and 640.66); and (6) adequate records were maintained to document unsuitable donors, and the performance of each significant step in the collection, processing, storage, and distribution of each unit of blood and blood components (21 CFR 606.160(a), 606.160(b), and 606.160(e)).

FDA received corrective action plans from BCI in letters dated March 26, 1993, and September 17, 1993. By letters dated May 19, 1993, August 26, 1993, and December 3, 1993, FDA, among other things, addressed BCI's proposed corrective action plans and provided the firm with explanations of why its proposals were inadequate.

In the December 3, 1993, letter, pursuant to 21 CFR 600.10, FDA informed BCI's responsible head that he had been deemed unsuitable for that position or any position of authority at the firm. Factors contributing to this decision included, but were not limited to: (1) The deviations cited in regard to the January through February 1993 inspection that resulted in license suspension; (2) failure to submit adequate corrective action plans; (3) failure to exercise control of the establishment in all matters relating to compliance; (4) failure to assure that personnel were adequately trained, properly supervised and had a thorough understanding of the procedures that they performed; and (5) a repeated history of license suspensions and revocations while responsible head of two other blood establishments.

In the May 13, 1994, letter, FDA made clear that the nature of the deficiencies at BCI, the firm's past history of noncompliance, the firm's failure to submit an adequate corrective action plan, and the unsuitability of the firm's responsible head demonstrated BCI's careless disregard for the applicable regulations and the applicable standards in its license. Due to this evidence of willfulness, based upon the evidence of careless disregard, and pursuant to 21 CFR 601.6, FDA was not required to provide BCI with further opportunity to correct its deficiencies and achieve compliance with the applicable standards.

In a letter dated May 13, 1994, FDA informed BCI of the agency's intent to revoke the firm's licenses and issue a notice of opportunity for a hearing pursuant to 21 CFR 601.5(b). BCI did not contact FDA within 10 days of receipt of the letter to voluntarily request revocation of its licenses. Pursuant to 21 CFR 12.21(b), FDA is now issuing a notice of opportunity for a hearing on a proposal to revoke U.S. License No. 1160 and the product licenses issued to BCI for the manufacture of Source Plasma and Source Leukocytes.

FDA has placed copies of letters supporting the proposed license revocation on file in the Dockets Management Branch under the docket number found in brackets in the heading of this notice. These documents include the following: FDA letters of March 19, 1993, May 19, 1993, August 26, 1993, December 3, 1993, May 13, 1994, and BCI letters of March 26, 1993, September 17, 1993, December 13, 1993, and February 16, 1994. 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.

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 proposed revocation of licenses are contained in 21 CFR parts 12 and 601. A request for a hearing may not rely upon mere allegations or denials but is required to set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

BCI may submit a written request for a hearing to the Dockets Management Branch by February 29, 1996, and any data or information justifying a hearing must be submitted by April 1, 1996. Other interested persons may submit comments on the proposed license revocation to the Dockets Management Branch by February 29, 1996. The failure of a licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

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 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351 (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701 (21 U.S.C. 321, 351, 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director and Deputy Director, Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: January 19, 1996.

Michael G. Beatrice,

Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–1656 Filed 1–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0369]

Memorandum on the Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995. In the memorandum, the Center for Biologics Evaluation and Research (CBER) recommends the implementation of donor screening tests for human immunodeficiency virus, type 1 (HIV–1) antigen(s) using licensed tests that are approved for donor screening. FDA is recommending the implementation of HIV–1 antigen screening because of the benefit that it will provide to a small number of blood product recipients, as a partial preventive measure against the possibility of any increase in HIV–1 ''window period'' donations and to decrease the virus burden in plasma pools for fractionation. FDA expects HIV–1 antigen testing will reduce, but not eliminate, the residual risk of HIV–1 from transfusion and, therefore, regards such screening as only an interim measure pending the availability of more advanced test methodology.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the memorandum to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or call FDA's automated information system at 800–835–4709. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the memorandum to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the memorandum and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to INTERNET may request the memorandum be sent by return E-mail by sending a message to ''HIVANTIGEN@A1.CBER.FDA.GOV''. The memorandum may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. CBER documents are maintained in a subdirectory called CBER on the server, ''CDVS2.CDER.FDA.GOV'' (150.148.24.202). The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the ''READ.ME'' file with a text-based FTP program would be:

FTP CDVS2.CDER.FDA.GOV
LOGIN: ANONYMOUS
<ANY PASSWORD> <''Your E-mail address''>
BINARY
CD CBER
GET READ.ME
EXIT

The memorandum may also be obtained by calling the CBER FAX Information System (FAX—ON—DEMAND) at 301–594–1939 from a touch tone telephone.

FOR FURTHER INFORMATION CONTACT: Paul A. Mied, Center for Biologics Evaluation and Research (HFM–310), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3008.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a memorandum to all registered blood and plasma establishments, dated August 8, 1995, recommending the implementation of donor screening for HIV–1 antigen with a licensed test approved for this use. As of August 8, 1995, there were no tests for HIV–1 antigen(s) approved for donor screening. However, FDA issued these recommendations in advance of the availability of such tests in order to provide blood and plasma establishments with maximum time to prepare for implementation of this testing. These recommendations supersede some of the rationale/recommendations provided in a previous FDA memorandum dated October 4, 1989, following licensure of the first test for HIV–1 antigen(s).

Based on the data available in 1989, FDA did not approve HIV–1 antigen testing for routine donor screening. Recently, however, the role of HIV–1 antigen testing in the donor setting has been reconsidered for several reasons. For instance, there have been four documented instances of HIV–1 transmission by HIV–1 antigen positive blood donations from three HIV–1 antibody negative donors. Also, based on recent estimates of the antibody negative infectious ''window period,'' the residual risk of HIV transmission by screened blood, and the efficacy of antigen testing to detect seronegative, infectious donations, it has been estimated that donor screening by HIV–1 antigen can be expected to prevent up to 25 percent of the current ''window period'' cases or about 5 to 10 cases of transfusion associated HIV infection per year.

In September 1994, FDA sponsored a ''Conference on the Feasibility of Genetic Technology to Close the HIV Window in Donor Screening.'' Although the majority of participating experts expressed the opinion that genetic techniques were not ready for use in mass screening, the meeting did spark renewed interest in considering other direct viral detection methods for donor screening, such as HIV–1 antigen testing as an interim measure to further reduce current low risk of