Dated: November 26, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30643 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0476]

Bavarian Red Cross; Revocation of U.S. License No. 1002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 1002), issued to the Bavarian Red Cross (BRC), for the manufacture of Whole Blood and Red Blood Cells. In a letter to FDA dated June 3, 2002, BRC voluntarily requested revocation of its licenses without prejudice and thereby waived its opportunity for a hearing. In a letter dated July 22, 2002, FDA revoked the firm's license.

DATES: The revocation of the biologics license (U.S. License No. 1002) is effective July 22, 2002.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has revoked the biologics license (U.S. License No. 1002), issued to BRC, Herzog-Heinrich-Strasse 4, D–80336, Munich, Germany, for the manufacture of Whole Blood and Red Blood Cells. Additional locations affected by the revocation include: Prof.-Ernst-Nathan-Str. 1, D–90419, Nurnburg, Germany; Klinikstrasse 5, D–97070, Wurzburg, Germany; Dr. Franz-Strasse 3, D–95445, Bayreuth, Germany; Westheimer Strasse 80, D–86156, Augsburg, Germany; Nikolaus-Fey-Strasse 32, D–97353, Wiesentheid, Germany; and Hoher Kreuz Weg 7, D–93055, Regensburg, Germany.

FDA inspected four of the six licensed locations of the BRC from October 27 through November 13, 1997. The inspections were conducted at the Munich, Wiesentheid, Nurnberg, and Bayreuth facilities. During the inspections, FDA observed significant deviations from the standards established in the license as well as the applicable Federal regulations. The standards and regulations are designed to ensure the continued safety, purity, and potency of the manufactured product. FDA also determined that the firm had discontinued the manufacture of Whole Blood and Red Blood Cells intended for distribution in the United States. FDA concluded that a meaningful inspection of BRC's ability to appropriately manufacture products under the license could not be made. The deviations noted during the inspections included, but were not limited to, the following: (1) In violation of 21 CFR 640.3(b), donor suitability was not adequately determined, in that questions were not asked, concurrently with the direct questions on high risk behavior, for exclusion of donors who are at increased risk for human immunodeficiency virus–1 (HIV–1) group O infection; (2) in violation of §§ 606.140, 610.40, and 610.45 (21 CFR 606.140, 610.40, and 610.45), inspections of the Nurnburg and Munich facilities disclosed that the Abbott Prism system, a device that was not approved by FDA, was utilized to test for antibody to HIV types 1 and 2 plus O (anti-HIV 1/2), the hepatitis B surface antigen (HBsAg), the antibody to hepatitis B core antigen (anti-HBc), and antibody to hepatitis C virus encoded antigen (anti-HCV). Additionally, blood and blood products were not tested for HIV–1 antigen and antibody to human lymphotropic virus type I (anti-HTLV–I); (3) in violation of § 606.140, the New LAV-Bolt I by Sanofi Diagnostics Pasteur, an HIV–1 western blot assay that was not approved by FDA, was used as an assay for reentry of donors; (4) in violation of § 606.140, the New LAV-Bolt II by Sanofi Diagnostics Pasteur, an HIV–2 western blot assay that was not approved by FDA, was used as an assay for reentry of donors; and (5) in violation of 21 CFR 606.121(c)(5)(i), blood and blood products that were intended for transfusion and collected from paid donors were not labeled as to distinguish them from blood products collected from volunteer donors.

In a letter dated July 8, 1998, and issued under § 601.5(b) (21 CFR 601.5(b)), FDA outlined the deviations noted at the inspection. FDA notified BRC of FDA's intent to revoke U.S. License No. 1002 and announced its intent to offer an opportunity for hearing unless the deviations were adequately addressed. In a letter to FDA dated July 30, 1998, BRC addressed FDA's concerns about the inability to inspect products prepared under the U.S. License No. 1002.

In a certified, return-receipt letter dated January 21, 1999, to BRC, FDA stated that the firm's July 30, 1998, response was inadequate to address all the violations that FDA documented at the inspections. FDA advised BRC that its response was unsatisfactory in that BRC had not provided a comprehensive corrective action plan, adequate to bring the firm into compliance with the applicable Federal standards and regulations. In the same letter, FDA suggested that the firm voluntarily request that U.S. License No. 1002 be revoked, and a new application be submitted at a later date.

In a letter dated November 3, 2000, FDA notified BRC that since the receipt of the July 30, 1998, letter to FDA, FDA had not received any additional response from the firm. The letter stated under § 601.5(b)(2), FDA had provided a reasonable period for the firm to demonstrate or achieve compliance with the applicable standards established in the license and regulations before proceeding to initiate revocation of U.S. License No. 1002. Since BRC did not submit a response addressing the methods intended to demonstrate or achieve compliance and did not waive an opportunity for hearing, FDA notified the firm in the same letter of FDA's intent to revoke the license and to issue a notice of opportunity for hearing under 21 CFR 12.21(b).

In the **Federal Register** of May 9, 2002 (67 FR 31348), FDA announced a notice of opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 1002) issued to BRC. In a letter to FDA dated June 3, 2002, BRC voluntarily requested revocation of its licenses without prejudice and thereby waived its opportunity for a hearing. In a letter to BRC dated July 22, 2002, FDA revoked the firm's license.

FDA had placed copies of the documents relevant to the revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document.

Accordingly, under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.202), the biologics license (U.S. License No. 1002) issued to BRC was revoked, effective July 22, 2002.

Dated: November 22, 2002.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 02–30642 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, Public Law 92–463), notice is hereby given of the following meeting. The meeting will be open to the public.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Date and Time: December 8, 2002, 7 p.m.–9 p.m. December 9, 2002, 8 a.m.–5:30 p.m. December 10, 2002, 8:30 a.m.–3 p.m.

Place: Wyndham Washington Hotel, 1400 M Street, NW, Washington, DC 20005.

Agenda: Agenda items will include, but not be limited to: Welcome, plenary session on bioterrorism and public health preparedness with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. Meeting content will address the critical nature of bioterrorism, current activities related to public health preparedness by the DHHS, state responses to bioterrorism and public health preparedness, and how the constituency groups of the committee are incorporating and will further incorporate bioterrorism and public health preparedness into their workforce education and training efforts. Proposed agenda items are subject to change as priorities dictate.

Public Comments: Public comment will be permitted before lunch and at the end of the Committee meeting on December 10, 2002. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Jennifer Donovan, Deputy Executive Secretary, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file a request in advance for a presentation, but wish to make an oral statement may register to do so at the Wyndham Washington Hotel, Washington, D.C., on December 10, 2002. These persons will be allocated time as the Committee meeting agenda permits.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Jennifer Donovan, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9–105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8044.

Dated: November 26, 2002.

Jon L. Nelson,

Associate Administrator for Management and Program Support.

[FR Doc. 02–30551 Filed 12–2–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at the following websites: *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–6870, (Formerly: Jewish Hospital of Cincinnati, Inc.).

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900.

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite