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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

[Docket No. 02N-0144]

Bavarian Red Cross; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 1002

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 biologics license (U.S. License No. 1002), issued to the Bavarian Red Cross (BRC), for the manufacture of Whole Blood and Red Blood Cells. The proposed revocation is based on the failure of the establishment and the product for which the license has been issued, to conform to the applicable standards established in the license and in the regulations.

DATES: The firm may submit written or electronic requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*], and any data and information justifying a hearing by [*insert date 60 days after date of publication in the Federal Register*]. Other interested persons may submit written or electronic comments on the proposed revocation by [*insert date 60 days after date of publication in the Federal Register*].

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: <http://www.fda.gov/dockets/ecomments>.

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.

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SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke 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 proposed 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. The proposed revocation is based on the failure of BRC to conform to the applicable standards established in its license and the requirements of parts 211 and 600 to 680 (21 CFR parts 211 and 600 to 680).

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 § 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, inspections of the Nurnburg and Munich facilities disclosed that the Abbott Prism system, a device 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 § 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), 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 a hearing unless the deviations were adequately addressed. In a letter to FDA dated July 30, 1998, BRC responded to FDA’s concerns about the inability to inspect products prepared under the U.S. License No. 1002.

In a certified, return-receipt letter to BRC, dated January 21, 1999, 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 that 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 a 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 a hearing under § 12.21(b) (21 CFR 12.21(b)).

Under § 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 1002) issued to BRC.

FDA has placed copies of the documents relevant to the proposed revocation on file with Dockets Management Branch (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. These documents include: (1) FDA's letters to BRC dated July 8, 1998, January 21, 1999, and November 3, 2000; and (2) BRC's response to FDA dated July 30, 1998. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

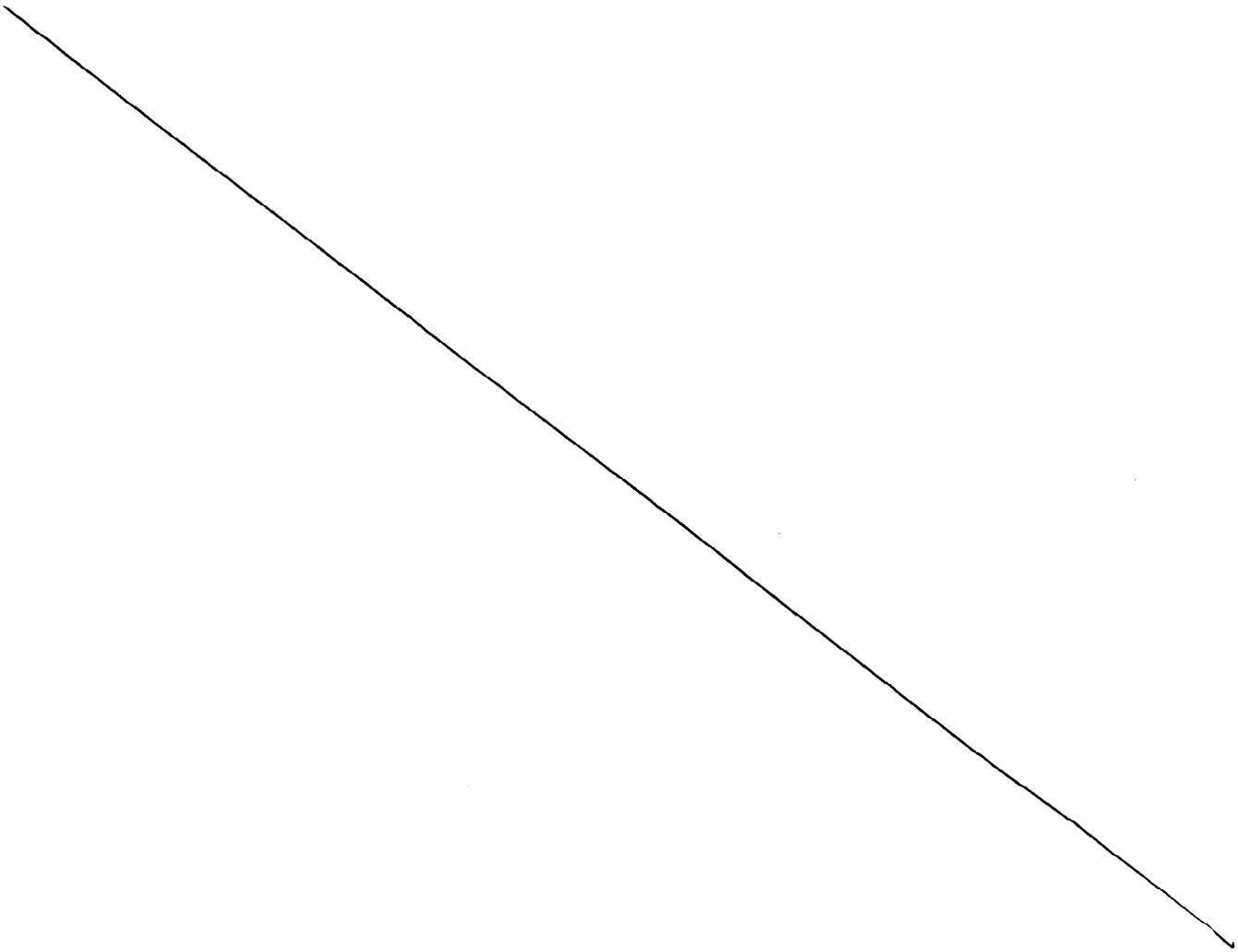
BRC may submit to the Dockets Management Branch (see **ADDRESSES**) a written request for a hearing by [*insert date 30 days after date of publication in the Federal Register*], and any data and information justifying a hearing must be submitted by [*insert date 60 days after date of publication in the Federal Register*]. Other interested persons may submit written comments on the proposed license revocation to the Dockets Management Branch by [*insert date 60 days after date of publication in the Federal Register*]. The failure of the 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.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If the Commissioner of the Food and Drugs (the Commissioner) determines upon review of any objections or request for a hearing that a hearing is not justified, in whole or in part, or if a request for a hearing is not made within the required

time with the required format or required analyses, the Commissioner will deny the hearing request, with an explanation for the denial.

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. Such 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 (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued 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 Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: 5/2/02
May 2, 2002.



Kathryn C. Zoon,
Director,
Center for Biologics Evaluation and Research.

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5-3-02

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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COPY OF THE ORIGINAL**

Dawn P. Hawkins