



**FOR FURTHER INFORMATION CONTACT:** Astrid L. Szeto, 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 is initiating proceedings to revoke the establishment license (U.S. License No. 11 16) and product licenses issued to Bestblood, Ltd., doing business as Optimum Healthcare, Inc., 239 Randall St., San Francisco, CA 94131, for the manufacture of Whole Blood, Red Blood Cells, Red Blood Cells Frozen, Whole Blood CPD, Red Blood Cells Deglycerolized, and Whole Blood CPDA- 1. Proceedings to revoke the licenses are being initiated because an attempted inspection of the facility by FDA, as required under §600.21 (21 CFR 600.21), revealed that the firm was no longer in operation.

In a certified, return-receipt letter dated June 16, 1997, FDA notified the Responsible Head of the firm that its attempt to conduct an inspection at Bestblood, Ltd., 239 Randall St., San Francisco, CA 94131, was unsuccessful because the facility was apparently no longer in operation, and requested that the firm notify FDA in writing of the firm's status. This letter was sent to 239 Randall St., San Francisco, CA 94131, and to P.O. Box 843, Cupertino, CA 95054-0843, and each was returned to the agent y as undeliverable.

In a certified, return-receipt letter sent to Bestblood, Ltd., dated March 4, 1998, at both addresses mentioned previously and returned as undeliverable, FDA indicated that an attempt to conduct an inspection at the facility was unsuccessful. The letter advised the Responsible Head that, under 21 CFR 601.5(b)(1) and (b)(2), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection required under §600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, proceedings for license revocation may be instituted. In the same letter, FDA indicated that a meaningful inspection could not be made at the establishment and issued the firm notice of FDA's intent to revoke U.S. License No. 1116 and announced its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding under 21 CFR 12.21(b) and publishing this notice of opportunity for a hearing on a proposal to revoke the licenses of the previously mentioned establishment.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include: (1) Summary of Findings, May 28, 1997 (Endorsement Form FDA 481), and (2) FDA letters to the Responsible Head dated June 16, 1997, and March 4, 1998. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Bestblood, Ltd., may submit a written request for a hearing to the Dockets Management Branch 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 a 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 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, or if a request for a hearing is not made within the required time with the required format or required

analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify 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 (address above) 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.

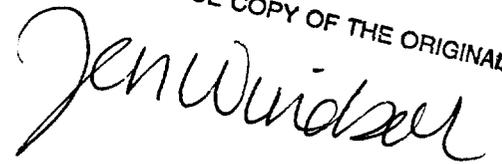
321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs (21 CFR 5. 10) and redelegate to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: 4/5/99  
April 5, 1999



Mark Elengold  
Deputy Director,  
Operations  
Center for Biologics Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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