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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-0671]

**Bestblood, Ltd.; Revocation of U.S. License No. 1116**

**AGENCY:** U.S. Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1116) and product licenses (the licenses) issued to Bestblood, Ltd., doing business as Optimum Healthcare, Inc., 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. Bestblood, Ltd., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

**DATES:** The revocation of the establishment license (U.S. License No. 1116) and product licenses is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Joseph L. Okrasinski, Jr., 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 revoking the establishment license (U.S. License No. 1116) 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 were initiated because an attempted inspection of the facility by FDA, as required under 21 CFR 600.21, revealed that the firm was no longer in operation.

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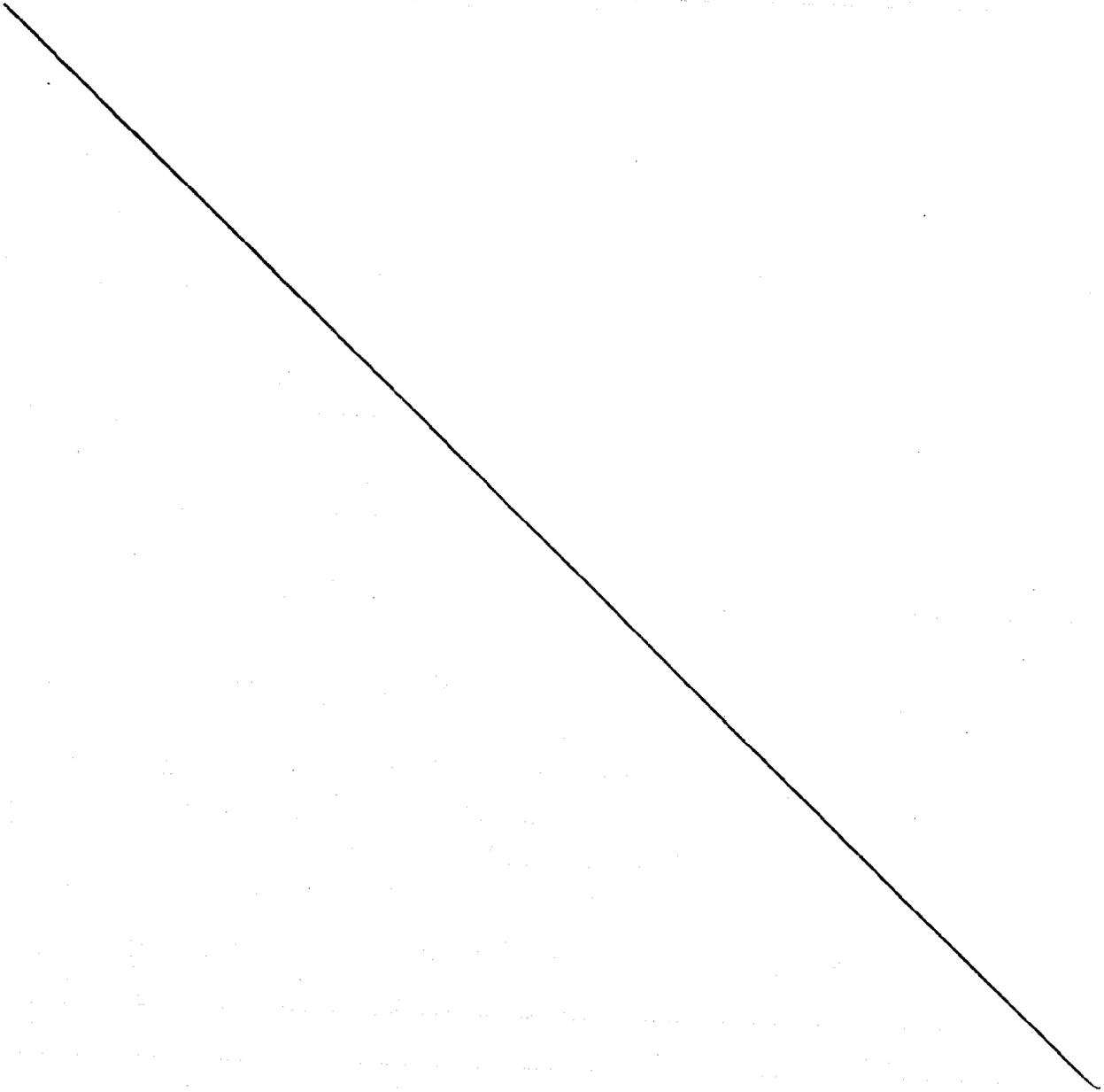
In a certified, return-receipt letter dated June 16, 1997, FDA notified the firm that the attempt to conduct an inspection at Bestblood, Ltd., 239 Randall St., San Francisco, CA 94131 was unsuccessful because the facility was apparently no longer in operation and requested that the firm notify FDA in writing of the firm's status. This letter was sent to 239 Randall St., San Francisco, CA 94131, and also to P.O. Box 843, Cupertino, CA 95054-0843, and each was returned to the agency 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 firm 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. FDA also indicated that a meaningful inspection could not be made at the establishment and issued to the firm a notice of FDA's intent to revoke U.S. License No. 1116 and announced its intent to offer an opportunity for a hearing.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of April 15, 1999 (64 FR 18623), a notice of opportunity for a hearing on a proposal to revoke the licenses of Bestblood, Ltd. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Documents Management Branch (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061 Rockville, MD 20852. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period

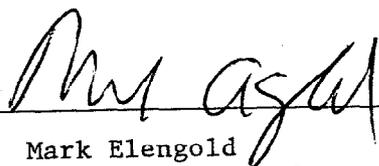
with a written request for a hearing. The 30-day time period prescribed in the notice of opportunity for a hearing and in the regulations, may not be extended. No other comments were received.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10)



and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68) the establishment license (U.S. License No. 1116) and the product licenses issued to Bestblood, Ltd., are revoked, effective [insert date of publication of the **Federal Register**].

Dated: 1/13/00  
January 13, 2000



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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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