

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1672]

DMB  
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Certifier R. LEDESMA

**Ashford Blood Bank, Inc.; Revocation of U.S. License No. 0740-001**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 0740-001) issued to Ashford Blood Bank, Inc., for the manufacture of Whole Blood and Red Blood Cells. Ashford Blood Bank, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its license.

**DATES:** The revocation of the biologics license (U.S. License No. 0740-001) 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.

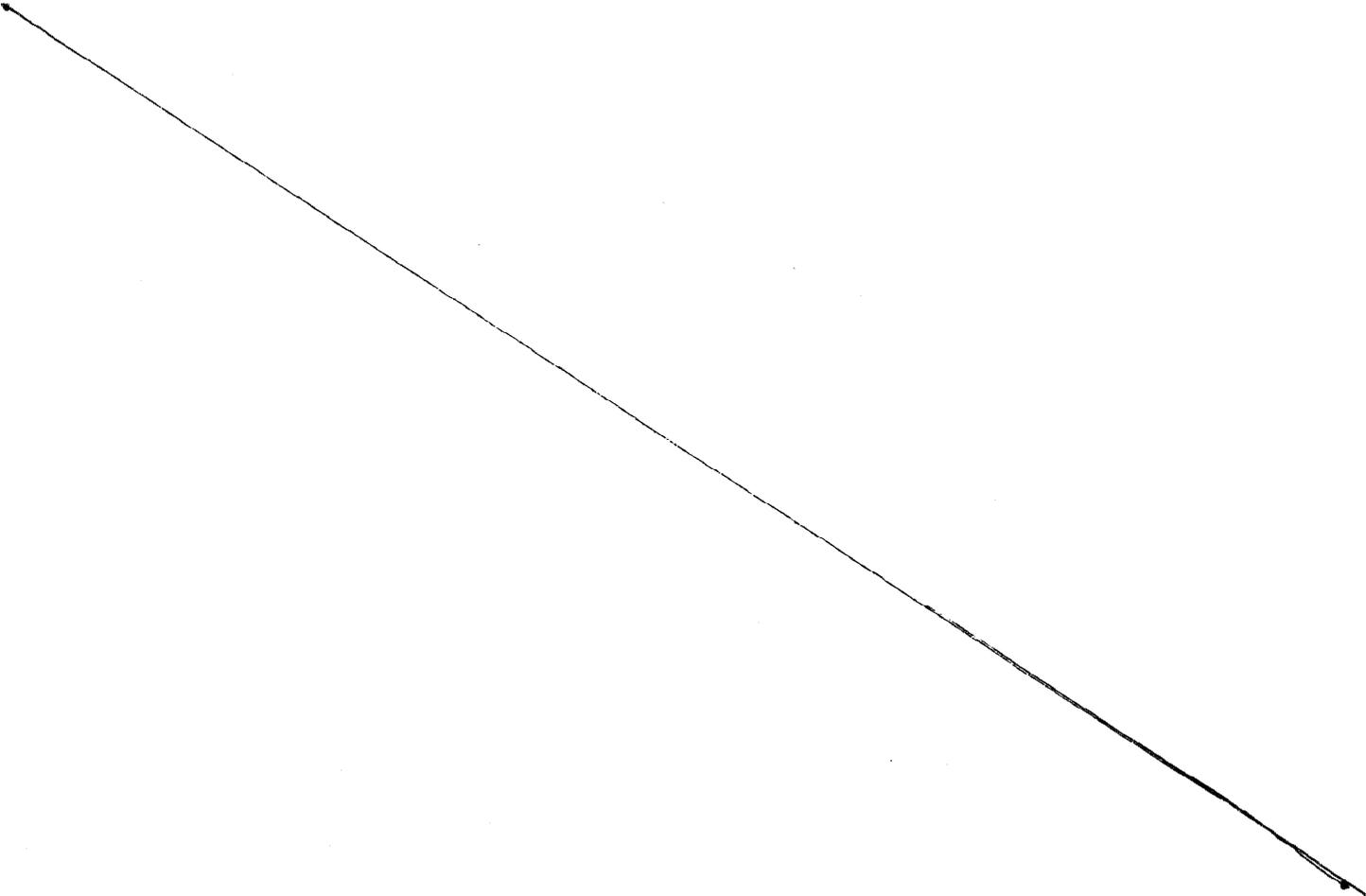
**SUPPLEMENTARY INFORMATION:** FDA is revoking the biologics license (U.S. License No. 0740-001) issued to Ashford Blood Bank, Inc., Ashford Medical Center, suite 401-402, Santurce, PR 00907, for the manufacture of Whole Blood and Red Blood Cells. FDA initiated proceedings to revoke the biologics license because: (1) Authorized FDA employees were unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility as mandated under § 600.21 (21 CFR 600.21), and (2) manufacturing of products had been discontinued to an extent that a meaningful inspection or evaluation could not be made. In a certified, return-receipt letter dated October 28, 1997, FDA notified an authorized official of the firm that FDA had suspended the establishment's biologics license for the manufacture of

Whole Blood and Red Blood Cells at its facilities at Santurce, PR, and Bayamon, PR. This action was based on the fact that significant deviations from the regulations were noted by FDA's San Juan district office during inspections of the facilities conducted August 19, 1997, through September 17, 1997, and September 9, 1997, through September 17, 1997, respectively. FDA's San Juan district office attempted to conduct additional inspections of the two Ashford facilities. On May 1, 1998, FDA investigators attempted to inspect the satellite collection facility at Bayamon, PR, but found that the facility was no longer in operation, and the manufacturing of Whole Blood and Red Blood Cells had been discontinued. On November 23, 1999, FDA investigators attempted to inspect the main facility in Santurce, PR, but found that the facility was no longer in operation and the manufacturing of Whole Blood and Red Blood Cells had been discontinued.

In certified, return-receipt letters dated April 13, 2000, sent to the establishment's facility at Santurce, PR, and also to the Ashford Blood Bank, Inc., P.O. Box 195034, San Juan, PR, 00919, FDA notified an authorized official of the firm that FDA's attempt to conduct inspections of the two facilities at Santurce, PR and Bayamon, PR were unsuccessful because the facilities were no longer in operation and the manufacture of Whole Blood and Red Blood Cells had been discontinued. The letter advised the establishment that, under § 601.5(b)(1) and (b)(2) (21 CFR 601.5(b)(1) and (b)(2)) (now codified as § 601.5(b)(1)(i) and (b)(1)(ii)), 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 could not be made at the establishment, FDA may initiate proceedings for license revocation. FDA also stated that a meaningful inspection could not be made at the establishment's facilities and issued to the establishment a notice of FDA's intent to revoke U.S. License No. 0740-001 and announced its intent to offer an opportunity for a hearing.

Under § 12.21(b) (21 CFR 12.21(b)), FDA published in the **Federal Register** of February 6, 2001 (66 FR 9087), a notice of opportunity for a hearing on a proposal to revoke the biologics

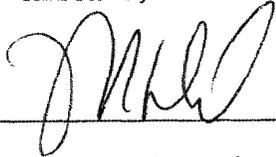
license of Ashford Blood Bank, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the establishment because it was no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The notice provided the establishment 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 establishment did not respond within the 30-day time period with a written request for a hearing, and under § 12.21(b), the 30-day time period prescribed in the notice of opportunity for a hearing 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), the biologics license (U.S. License No. 0740-001) issued to Ashford Blood Bank, Inc., is revoked, effective [*insert date of publication in the Federal Register*].

Dated: 3/6/02

March 6, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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

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