

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DWB

Display Date	2/5/01
Publication Date	2/6/01
Certifier	<i>[Signature]</i>

[Docket No. 00N-1672]

**Ashford Blood Bank, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S.**

**License No. 0740-001**

**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 establishment license (U.S. License No. 0740-001) and product licenses issued to Ashford Blood Bank, Inc., for the manufacture of Whole Blood and Red Blood Cells. The proposed revocation is based on the fact that authorized FDA employees have been unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility and that the manufacturing of products has been discontinued to an extent that a meaningful inspection or evaluation cannot be made.

**DATES:** The firm may submit written 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 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.

*NOH-1*

**FOR FURTHER INFORMATION CONTACT:** Joseph L. Okrasinski, 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. 0740-001) and product licenses 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. Proceedings to revoke the licenses are being initiated because: (1) Authorized FDA employees have been unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility, and (2) manufacturing of products has been discontinued to an extent that a meaningful inspection or evaluation cannot 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 firm's establishment and product licenses 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 firm'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 attempts 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 also advised the authorized official that, under 21 CFR 601.5(b)(1) and (b)(2) (now codified as 21 CFR 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 under 21 CFR 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, the Commissioner of Food and Drugs (the Commissioner) shall institute proceedings for license revocation. In the same letter, FDA stated that a meaningful inspection could not be made at the establishment and notified the firm of FDA's intent to revoke U.S. License No. 0740-001 and its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and has not received any response from the firm to the revocation letter, 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 firm.

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 1, 1998; (2) memorandum regarding FDA visit to Santurce location, November 23, 1999; and (3) FDA letters to the authorized official dated October 28, 1997, and April 13, 2000. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Ashford Blood Bank, Inc., 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.

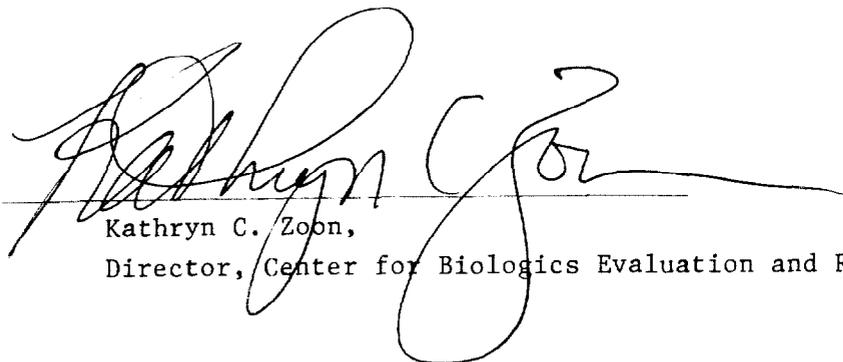
FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact. If the Commissioner determines upon review of any objections or requests 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 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 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 5.67).

Dated: January 24, 2001.



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

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

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